IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIOID LITIGATION	MDL No. 2804 Case No. 17-md-2804
CITY OF CLEVELAND OHIO and THE STATE OF OHIO EX REL. ET AL Plaintiffs, v. PURDUE PHARMA L.P., ET AL Defendants.	Judge Dan Aaron Polster

AMENDED EXPERT REPORT OF SANDRA K.B. KINSEY, R.Ph, MBA.

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I. INTRODUCTION

1. I, Sandra Kinsey, have been retained by and submit this expert report on behalf of Defendant HBC Service Company ("HBC"), which is owned and operated by Giant Eagle, Inc. ("Giant Eagle") in the above-captioned litigation.

2. The opinions and analysis in this report are based on currently available documents and information. I reserve the right to supplement and/or amend my opinions herein based on any statements, testimony, positions, and opinions advanced by Plaintiffs, its experts and/or witnesses, including any rebuttal to this report. Moreover, in the event there are subsequent developments in this litigation that bear on my opinions and views, such as, for example, additional discovery that occurs or additional information is otherwise made available to the parties, I reserve the right to supplement this report to take those developments into consideration. I also reserve the right to make and use demonstrative aids or exhibits to help explain my opinions and/or testimony.

3. If called upon, I am prepared to testify about my background, qualifications, and experience as well as about the issues and opinions described in this Report. Furthermore, I anticipate that I may be asked to provide testimony and to consider and respond to arguments that Plaintiffs' expert(s) or fact witnesses may raise in reports and/or at any hearing.

A. My Background and Qualifications

4. I am an expert with a particular expertise in matters relating to the retail pharmacy market, pharmacy operations, merchandising, financial, marketing, wholesale distribution, and product procurement and supply chain. I have more than 25 years of experience in the retail pharmacy industry. I have served as an expert in numerous cases that relate to retail pharmacy operations and inventory management, including claims such as patent infringement, false advertising, and prescription errors. The following is a brief summary of my background,

experience and achievements, which are more fully set out in my *curriculum vitae*, a copy of which is attached as Exhibit A.

5. I received a Bachelor of Science in Pharmacy in 1992 from the University of Missouri, Kansas City and an MBA from Kaplan University in 2008. I have been a Registered Pharmacist in Kansas since 1992 and became a licensed Pharmacy Doctor in Arkansas in 1996. Both licenses are current, and I actively practice in the state of Arkansas.

6. Until 2014, I was Vice President of Pharmacy Merchandising, Health & Wellness for Walmart, Inc. in Bentonville, Arkansas. I was responsible for all prescription product procurement, preferred formulary development, distribution and supply chain, pricing, and inventory management for over 5,000 stores. During my 17-year career at Walmart, I acquired a breadth of retail pharmacy experience by serving in a variety of roles within Pharmacy Operations, Merchandising, Technology, and Compliance.

7. In 2014, I founded Kinsey Partners, LLC, a retail healthcare consulting firm, where I am currently the president. At Kinsey Partners, I assist industry leaders in developing comprehensive strategies for growth within the retail and healthcare sectors. My contract clients include major retail pharmacies, pharmaceutical companies, and drug wholesalers. I also consult and provide expert opinion through my position at Kinsey Partners.

8. Being a registered pharmacist in Arkansas and Kansas, I also work in stores with independent pharmacists on prescription filling, operational processes, regulatory compliance, technology infrastructure, third party insurance negotiations and billing, customer service, and other related services.

9. In addition, I am a clinical pharmacist for Highlands Oncology Group, a nationally recognized cancer treatment center. In this position, I regularly care for patients with extensive acute and chronic pain relief needs at various stages of illness.

10. Based on my education, practical training, teaching, research, editorial work, consulting, and industry experience, I consider myself an expert in the areas of retail pharmacy operations, prescription filling, product sourcing, inventory management and supply chain.

B. Prior Testimony and Compensation

11. A copy of my prior expert testimony and work as a subject matter expert is attached as Exhibit B.

12. I have served as an expert on eight cases, with claims including patent infringement, trademark infringement, false advertising, breach of contract, anticompetitive conduct, and antitrust violations. During the past four years, I testified at four trials and I was deposed in the following case(s):

- *Heartland Medical LLC vs. Express Scripts, Inc.*,
  Case No. 17CV02873, District Court of Missouri, November 2018
- *Valeant Pharmaceuticals LLC vs. ECI Pharmaceuticals LLC and Virtus Pharmaceuticals LLC,*
  Case No. 18CV00355, North District of California
  Investigation No. 337TA1109, International Trade Commission, June 2018
- *Takeda Pharmaceuticals Inc. vs. West-Ward and Hikma Pharmaceuticals Inc.*,
  Case No. 14CV01268, District Court of Delaware, March 2018
- *Winder Laboratories LLC and Steven Pressman vs. Concordia Pharmaceuticals,*
  Case No. 16CV00004, District Court of Georgia, Gainesville Division, April 2018
- *GlaxoSmithKline Inc. vs. Teva Pharmaceuticals Inc.,* Case No. 14CV00878,
  District Court of Delaware, December 2016
- *GlaxoSmithKline Inc. vs. Glenmark Pharmaceuticals Inc.,* Case No. 14CV00877,
  District Court of Delaware, December 2016

- *Concordia Pharmaceuticals Inc. vs. Winder Laboratories LLC and Steven Pressman*, Case No. 16CV00004, District Court of Georgia, Gainesville Division, March 2016

13. I am being compensated at my customary hourly rate of $500 for expert consulting on this matter. I expect to be compensated at the same rate for my time spent testifying by deposition or at any hearing. My compensation has not influenced my view on any of my opinions set forth herein and is not dependent on the outcome of the Investigation.

C. Materials Considered and Preparation

14. The opinions and the statements I make in this Report are based on my personal knowledge, education and training, and professional experience. In addition, I rely on and incorporate by reference the documents and information cited in the Report itself and listed in Exhibit C.

D. Assignment

15. I have been asked by counsel to provide an overview of the opioid pharmaceutical market, with concentration on hydrocodone/acetaminophen combination drugs, and the benefits of these products when responding to patient relief of moderate to severe pain. I will also describe the relative role of health care providers, pharmacy dispensing practices, and the benefits of a closed distribution supply chain to not only ensure adequate inventory for patient care, but also to comply with the provisions listed in the Controlled Substances Act to prevent theft and diversion.

16. More specifically, I reviewed the operational infrastructure of Giant Eagle's pharmacy, which consists of a separate and distinct business within a larger grocery chain. I was asked to opine on their systems of integrated controls that have evolved over the years with advancements in technology, physical infrastructures, and general business practices as it relates to compliance with the Controlled Substances Act (CSA).

E. Summary of Expert Opinions

17. Based on my education and experience, information produced in this litigation and publicly available information, I conclude:

a) As a board licensed pharmacist with over 25 years of experience, I find that opioids are effective and essential drugs for pain management when used appropriately. The vast majority of opioid prescriptions are written for legitimate reasons and consumed by patients according to prescribers' directions without undue or long-lasting harm to the patient.

b) Patients are increasingly aware of the benefits and risks of pain medications, including opioids. Patients receive verbal and written information from their prescriber and pharmacist that detail precautions and side effects associated with opioid use. Most understand the growing concern surrounding these products and the need to safeguard their personal prescriptions from theft, diversion and misuse.

c) The first line pharmacologic agent for symptom relief of mild to moderate pain is acetaminophen (Tylenol™) or a non-steroidal anti-inflammatory drug (Motrin™/ibuprofen). If pain is not resolved or is expected to be moderate to severe intensity, evidence-based treatment protocols recommend opioid/acetaminophen combination products.[1] As the mildest

[1] Bondell, R., Azadfard, M., and Wisniewski, A. Pharmacologic Therapy for Acute Pain. *American Family Physician*. 2013 Jun 1:87(11):766-772, *available at* https://www.aafp.org/afp/2013/0601/p766 html (last accessed May 3, 2019).

dose, hydrocodone containing products (HCP), like Norco™, are the most frequently prescribed drugs for pain relief.[2]

d) Pharmacies play an essential role in patient care. Besides dispensing prescriptions, pharmacists are an integral part of the communication process between doctor, manufacturer, insurer, regulatory agencies and patient, ensuring efficacy, safety and access to every drug they dispense for every patient to which they extend care.

e) Prescriptions are written and dispensed by highly educated, licensed health care providers that complete annual certifications for practice by their respective state governing boards. Distributors and pharmacies are licensed by state and federal authorities and are inspected yearly for compliance to all legal regulations. These key stakeholders regularly receive and complete compliance training that details procedures for the prevention of theft and diversion of opioid prescriptions.

f) As part of the prescription filling process, a pharmacist often communicates with prescribers regarding an opioid prescription to discuss the drug, strength, dose or frequency of utilization for a specific patient. Referencing information from a patient's insurance company, national and state opioid databases, or through experience, a pharmacist may refuse to fill a prescription that appears inappropriate based on their professional judgment.

[2] Hydrocodone (2018). Drug Enforcement Administration Diversion Control Division, available at https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf (last accessed May 4, 2019).

g) The Controlled Substances Act (CSA) requires all applicants and registrants to provide effective controls and procedures to guard against theft and diversion (the "Security Requirement")[3]. Substantial compliance with the Security Requirement is based upon an overall evaluation of the security system and needs of the registrant using a combination of factors including: the type of activity conducted; the type, form and quantity of controlled substances handled; the type and location of the facility; the types of secure enclosures; detection and alarm systems; and the adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations. The DEA has left it substantially to the discretion of each registrant to design and operate its system to comply with the Security Requirement, and such system must be able to disclose suspicious orders when discovered[4]. Policies and procedures for compliance with all requirements of the CSA have evolved over the years and will continue to change with advancements in technology, physical infrastructures, and general business practices.

h) Captive self- distributors for prescription products fulfill orders that will replenish shelf stock for items that have already been dispensed. Therefore, artificially limiting order quantities, preventing shipments and delaying orders unnecessarily can interrupt patient care and cause further harm.

[3] 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.71.
[4] 21 C.F.R. §§ 1301.74.

i) Giant Eagle is a small grocery chain with a relatively small pharmacy business. Recognizing the complex differences to the core organization, Giant Eagle built a pharmacy infrastructure that is separate from its main grocery business in order to focus on patient care, prescription delivery and cost, supply chain, regulatory compliance, training and other health related business services. This independence enables the pharmacy to operate with efficiency and accuracy because of the redundant layers of oversight by specially trained and educated employees.

j) Giant Eagle's inventory management system consists of integrated controls within the corporate office, distribution center and pharmacy to prevent theft and diversion of all prescription products. Because of the heightened sensitivity concerning controlled substances, and opioids in particular, additional parameters are engaged that exceed regulatory minimums.

k) Giant Eagle is, and always has been, compliant with the Controlled Substances Act as evident by their continued licensing by the Ohio State Board of Pharmacy, the Pennsylvania, West Virginia, Maryland and Indiana State Boards of Pharmacy and the Drug Enforcement Agency for every store in the respective states as well as for the HBC Services Company (HBC) and Giant Eagle Rx (GERx) distribution centers. Because of their robust and cohesive processes to prevent theft and diversion before it occurs, it is not surprising that only a limited number of

orders were identified as part of their comprehensive design of SOM systems and safety controls.

II. OVERVIEW OF THE OPIOID MARKET

A. A Brief Review of Opioids and the Controlled Substances Act

18. Opioids have been regarded for millennia as among the most effective drugs for the treatment of pain.[5] Opioids are a group of narcotic pain-relieving drugs which act by interacting with opioid receptors in the brain, spinal cord and other areas of the body to interrupt the pain response pathway. Opioids can be made from the poppy plant, such as morphine, or synthesized in a laboratory, such as fentanyl. Opioids are used as an anesthesia, cough suppressant, diarrhea suppressant and for the management of pain arising from various diseases and injuries.[6] According to the National Institutes of Health, a division of the U.S. Department of Health and Human Services (HHS), opioids are "generally safe when used for a short time and as prescribed by a doctor."[7]

19. According to research from 2016, the opioid market is witnessing growth due to increasing prevalence of orthopedic diseases and other chronic pain afflictions, rising focus on abuse-deterrent formulations, growth of palliative care initiatives and facilities, and an inclination toward extended release formulations from the immediate release alternatives.[8]

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[5] Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology, 16*(5), 405-416, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/ (last accessed May 3, 2019).

[6] Opioids Market by Product (Morphine, Codeine, Fentanyl, Meperidine), Receptor Binding (Strong Agonist, Mild to Moderate Agonist), Application (Pain Management, Cough Suppression, Diarrhea Suppression), Region (North America, Europe, Asia, RoW) – Global Forecasts to 2023, *available at* https://www marketsandmarkets.com (last accessed May 3, 2019).

[7] How Opioid Drugs Activate Receptors (2018), *available at* https://www nih.gov/news-events/nih-research-matters/how-opioid-drugs-activate-receptors (last accessed May 3, 2019).

[8] Opioids Market by Product (Morphine, Codeine, Fentanyl, Meperidine), Receptor Binding (Strong Agonist, Mild to Moderate Agonist), Application (Pain Management, Cough Suppression, Diarrhea Suppression), Region (North America, Europe, Asia, RoW) – Global Forecasts to 2023, *available at* https://www marketsandmarkets.com (last accessed May 3, 2019).

However, factors such as prescription drug abuse and misuse and the corresponding increases in regulations will create offsets as prescribing authority and insurance reimbursements are limited. The unintended consequence of these restrictive regulations also impacts patient care by creating additional complexity to access and treatment, forcing patients to suffer or seek medication from illegal sources.

20. Recognizing the harm caused by certain drugs and the need to consolidate more than 200 separate laws, President Richard Nixon signed the Controlled Substances Act (CSA) in 1970, combining all prior existing federal drug laws into one consistent statute.[9] The CSA is administered and enforced by the Drug Enforcement Agency (DEA) and it regulates the manufacture and distribution of controlled substances and categorizes drugs into five classifications or "schedules" based on, *inter alia*, their medical significance and potential for abuse.[10]

21. Schedule I drugs are deemed to have no currently accepted medical value and a high potential for abuse. Examples include heroin, LSD and ecstasy.

22. Schedule II drugs provide medical value and a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Some examples include cocaine, methamphetamine, oxycodone, and fentanyl.

23. Substances with progressively less potential for harm and abuse were placed in Schedules III through V respectively.

24. When Congress passed the CSA in 1970, it placed hydrocodone containing products (HCPs) in Schedule III. However, after more than 40 years, due to the many findings

[9] Van Dusen, V. and Spies, A. An Overview and Update of the Controlled Substances Act of 1970. Pharmacy Times (2007), *available at* https://www.pharmacytimes.com/publications/issue/2007/2007-02/2007-02-6309 (last accessed May 3, 2019).
[10] 21 U.S.C. § 812 and 21 C.F.R. §§ 1301.

by the Drug Enforcement Administration (DEA) and the United States Department of Health and Human Services (HHS), HCP was eventually moved into Schedule II in 2014 in response to the ever-growing problem of abuse and misuse.[11]

25. Today, experts say the United States is in the throes of an opioid epidemic. According to the Centers for Disease Control and Prevention, from 1999 to 2017, almost 400,000 people died from an overdose involving opioids, including prescription and illicit opioids[12]. Referencing Table 1, this rise in overdose deaths can be outlined in three distinct waves:

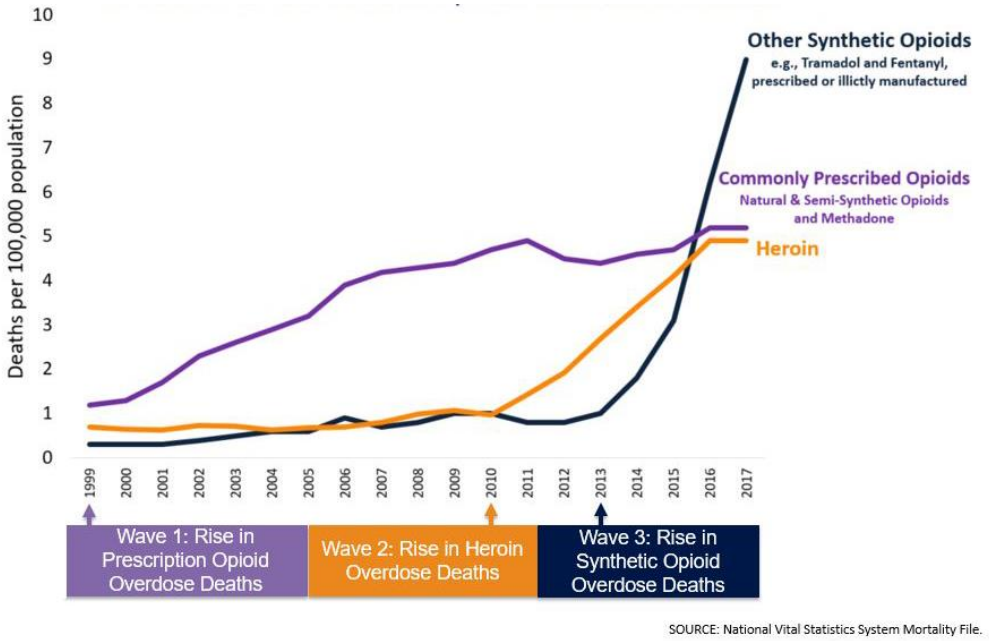
(i) The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths mainly involving prescription opioids.

(ii) The second wave began in 2010, with rapid increases in overdose deaths involving heroin.

(iii) The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids – particularly those involving illicitly manufactured fentanyl.[13]

[11] DEA To Publish Final Rule Rescheduling Hydrocodone Containing Products (2014). United States Drug Enforcement Administration, *available at* https://www.dea.gov/press-releases/2014/08/21/dea-publish-final-rule-rescheduling-hydrocodone-combination-products (last accessed May 3, 2019).
[12] Opioid Overdose. Understanding the Epidemic. Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/drugoverdose/epidemic/index html (last accessed May 3, 2019).
[13] Opioid Overdose. Understanding the Epidemic. Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/drugoverdose/epidemic/index html (last accessed May 3, 2019).

Table 1: The Waves of the Rise in Opioid Overdose Deaths



26. Opioids play a unique role in society. The Food and Drug Administration (FDA) comprehensively regulates prescription drugs in the United States. Although the FDA has approved and continues to approve opioids for efficacy and safety, they have become widely feared compounds by healthcare providers and patients, not because of concerns for the active chemical compound and related side effects, but because of the association with abuse, addiction and the dire consequences of diversion. These drugs are also essential medications and the most effective drugs for the relief of pain and suffering.[14]

27. According to the DEA, the overwhelming majority of prescribers act responsibly with regards to opioid prescriptions and that 99.5% of prescribers do not overprescribe these medications.[15]

[14] Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology, 16*(5), 405-416, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/ (last accessed May 3, 2019).
[15] Deposition of Thomas Provoznik, dated April 17-18, 2019, pp. 400-403 and 436-441.

28. To raise awareness and help manage this "crisis", a plethora of trade associations, advocacy groups, and special interest organizations have engaged in developing and distributing patient education and engagement resources that instruct patients to safeguard their prescriptions responsibly. Specifically, the information asks patients to help prevent misuse and abuse by 1) never selling or sharing prescription medications, 2) never using another person's prescription opioids, 3) store medications in a secure place and out of reach of others, including visitors, friends and family, and 4) safely dispose of unused prescription opioids at a community take-back location.

B. Evolution of Pain Management

29. During most of the twentieth century, the widely held perception among health care professionals in the United States was that the long-term use of opioid therapy to treat chronic pain was contraindicated by the risk of addiction, increased disability and lack of efficacy over time.[16]

30. During the 1990's, a major change occurred, driven by a variety of medical and nonmedical factors. The use of opioids for chronic pain began to increase, showing a substantial year-to-year rise that continues today[17]. This increased use of opioids for legitimate medical purposes has been accompanied by a substantial increase in the prevalence of nonmedical use of prescription opioids. Although the increase in prescription drug abuse is likely to be multifactorial, it is likely to reflect, in part, changes in available drug formulations and

[16] Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology, 16*(5), 405-416, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/ (last accessed May 3, 2019).

[17] Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology, 16*(5), 405-416, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/ (last accessed May 3, 2019).

prescribing practices of opioid medication. This link between increased medical use and increased abuse has driven some of the re-examination of the medical role of these drugs.

31. In 1986, the World Health Organization (WHO) presented the analgesic ladder as a framework that physicians could use when developing treatment plans for cancer, paving the way for considerable improvements in the management of pain. The WHO designed the analgesic ladder following the recommendations of an international group of experts. The document was eventually translated into 22 different languages and has served as a catalyst for increasing awareness around the world of the importance of treating pain in cancer patients.[18]

32. The analgesic ladder proposes the use of a limited number of relatively inexpensive medications, such as hydrocodone, in a stepwise approach. It helped legitimize the use of opioids for treatment of cancer pain and encouraged numerous worldwide teaching campaigns on the use, benefits, and side effects of narcotics in the treatment of pain.

33. According to recommendations, the first line pharmacologic agent for symptom relief of mild to moderate pain is acetaminophen (Tylenol™) or a non-steroidal anti-inflammatory drug (Motrin™/ibuprofen). If pain is not resolved or is expected to be moderate to severe intensity, evidence-based treatment protocols recommend opioid/acetaminophen combination products.[19] As the mildest opioid product, hydrocodone containing products (HCP), like Norco™, are the drugs most frequently prescribed by doctors for pain relief.[20]

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[18] Vargas-Schaffer G. Is the WHO analgesic ladder still valid? Twenty-four years of experience. *Can Fam Physician*. 2010;56(6):514–e205, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2902929/ (last accessed May 4, 2019).

[19] Bondell, R., Azadfard, M., and Wisniewski, A. Pharmacologic Therapy for Acute Pain. *American Family Physician*. 2013 Jun 1:87(11):766-772, *available at* https://www.aafp.org/afp/2013/0601/p766 html (last accessed May 3, 2019)

[20] Hydrocodone (2018). Drug Enforcement Administration Diversion Control Division, available at https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf (last accessed May 4, 2019).

34. Despite the debate and updates to the 1986 analgesic diagram, its educational value and the benefits resulting from its worldwide dissemination are uncontested. Adaptations of the original ladder include treatments for acute and chronic non-cancer pain, and include consideration of invasive techniques, such as nerve blocks and neurolysis.[21]

35. However, the continuing challenge is to reduce the likelihood of opioid misuse while not imposing barriers on the legitimate use of opioid medications. There is concern that the pendulum has swung from undertreatment to overtreatment. This controversy is enhanced by the increased prevalence of prescription opioid abuse, which has developed concomitantly with an increase in opioid administration in the clinic. The resolution of this controversy will require much more research and the acceptance of treatment guidelines that recognize the dual obligations of the prescriber: to optimize the balance between analgesia and side effects, and promote other favorable outcomes, while concurrently assessing and managing the risks associated with abuse, addiction and diversion.

C. Practitioners, Education, Licensing and Governing Boards

36. The requirements for becoming a doctor in the United States may vary by specialty. In general, doctors complete a four-year undergraduate degree program, spend 4 years in medical school, and then complete three to seven years of residency training before they are eligible for medical licensing. Further education and residency years may be required as the individual pursues a specific specialty and area of practice.

37. Medical school consists of four years of medical training and education. The first two years of a prospective doctor's medical school experience are devoted to book study and

[21] Vargas-Schaffer G. Is the WHO analgesic ladder still valid? Twenty-four years of experience. *Can Fam Physician*. 2010;56(6):514–e205, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2902929/ (last accessed May 4, 2019).

laboratory work to prepare students for diagnosing and treating illnesses. During the second year of medical school, students take the first portion of the United States Medical Licensing Examination, which is administered by the National Board of Medical Examiners.[22]

38. During the last two years of medical school, students begin their clinical experience, completing a series of rotations at clinics and hospitals. Students work under attending physicians to begin their practical training in medicine. During the fourth year of medical school, the seconding licensing test is issued and residency training begins.[23]

39. Most doctors complete their residency in a three to seven-year period, depending on specialization. As part of the first year of residency, the final medical licensing exam is given, while the residency itself focuses on practical training in a medical environment, rather than classroom learning. Post-residency fellowships may be pursued for advancement and accreditation in certain specialties.

40. State medical boards are the agencies that license medical doctors, investigate complaints, discipline physicians who violate the medical practice act, and refer physicians for evaluation and rehabilitation when appropriate. The overriding mission of medical boards is to serve the public by protecting it from incompetent, unprofessional, and improperly trained physicians. Medical boards accomplish this by striving to ensure that only qualified physicians are licensed to practice medicine and that those physicians provide their patients with a high standard of care.[24]

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[22] "Requirements to Become a Doctor in the U.S., *available at* https://study.com/requirements_to_become_a_doctor.html (last accessed May 4, 2019).
[23] "Requirements to Become a Doctor in the U.S." *available at* https://study.com/requirements_to_become_a_doctor.html (last accessed May 4, 2019).
[24] Carlson, D. and Thompson, J. The Role of State Medical Boards. *Virtual Mentor*. 2005;7(4):311-314.doi: 10.1001/virtualmentor.2005.7.4.pfor1-0504, *available at* https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04 (last accessed May 4, 2019).

41. The right to practice medicine is a privilege granted by the state. Each state has laws and regulations that govern the practice of medicine and specify the responsibilities of the medical board in regulating that practice. These regulations are laid out in a state statute, usually called a medical practice act. State medical boards establish the standards for the profession through their interpretation and enforcement of this act. All prescribing practitioners must be licensed by a state medical board, and if writing for controlled substances, must be registered with the DEA.

42. In addition, all licensed health care providers must submit for license renewal on a regular basis and must, *inter alia*, complete profession specific continuing education. The State Medical Board of Ohio requires license renewal every two years and the doctor applicant must have completed a minimum of 100 continuing medical education to be considered for license renewal.[25]

43. Like doctors, pharmacists also complete rigorous education. Pharmacists graduating from college today are required to have a Doctor of Pharmacy (PharmD) degree. College students can start a four-year program after successfully completing two years of undergraduate work and earning a passing score on the Pharmacy College Admission Test. In reality, however, many students do not decide on a profession in the early years of college, and therefore earn their degree in seven or eight years. Additionally, PharmD students must complete a series of rotations in a variety of clinical and pharmaceutical settings.

44. To prove competency and receive a license to practice, a pharmacist must pass the North American Pharmacist Licensure Examination, which measures a candidate's knowledge of the practice of pharmacy and pass the Multistate Pharmacy Jurisprudence Examination, which

[25] "Physician Renewal and Continuing Medical Education (CME) Chart." State Medical Board of Ohio *available at* https://med.ohio.gov (last accessed May 4, 2019).

combines federal and state-specific questions to test the legal and ethics knowledge of prospective pharmacists. It serves as the pharmacy law examination in participating jurisdictions and tests a candidate's mastery of pharmacy law.

45. In addition, each pharmacist is governed and licensed by the respective state board of pharmacy for each state in which they practice. And like doctors, pharmacists must complete state mandated hours of continuing education when applying for license renewal annually or biennially. Many boards of pharmacy, including the State of Ohio Board of Pharmacy, mandate annual compliance training for all staff involved with controlled substances on how to identify and protect against theft and diversion.

46. The State of Ohio Board of Pharmacy is responsible for administering and enforcing the drug laws of Ohio, which includes the licensing of pharmacists, pharmacy interns, terminal and wholesale distributors of dangerous drugs.[26]

47. Other healthcare professions follow the same structure, with varying degrees of education, examination and licensure. Most all are governed by and licensed by the state after proof of competency on an annual or biennially.

III. OVERVIEW OF GIANT EAGLE

A. History and Locations

48. Giant Eagle is a family-built chain of grocery stores that began in the early 1930s and spread quickly throughout the Pittsburgh area.[27] Currently, Giant Eagle operates retail locations in western Pennsylvania, north central Ohio, northern West Virginia, Maryland, and Indiana.[28]

[26] Licensing/CE. State of Ohio Board of Pharmacy, *available at* https://www.pharmacy.ohio.gov/Licensing/General.aspx (last accessed May 4, 2019).
[27] https://www.gianteagle.com/about-us/our-history (last accessed May 3, 2019).
[28] https://www.gianteagle.com/about-us/press-room (last accessed May 3, 2019).

49. As self-proclaimed "Pioneers of the Modern Supermarket", Giant Eagle continually innovates with store design, technology advancements and new service offerings for customer convenience and loyalty. In the 1980s, Giant Eagle built upon the store-within-a-store concept by adding pharmacy, floral, automotive, housewares, books, greeting cards, photo development and video rentals.[29] Giant Eagle also built the world's first LEED-certified supermarket, receiving numerous local, state, and federal awards for its commitment to environmental sustainability and waste reduction.[30]

50. Giant Eagle operates more than 400 retail locations of various sizes, including 120,000 square-foot supermarkets to small neighborhood markets, as well as fuel and convenience locations[31]. Within the enterprise, Giant Eagle operates only 227 pharmacies.[32]

51. Even with its relatively small footprint, Giant Eagle is recognized as one of the 20 most influential retailers in the United States.[33] Among other highlights, Giant Eagle is praised for their pharmacy offerings and their ability to successfully compete against Rite Aid, once the third-largest retail drugstore chain in the country and headquartered in Pennsylvania.[34] Industry leaders regard Giant Eagle as the "perfect combination of pharmacy, food and fuel as something to really give value to consumers in their greater Pennsylvania, Ohio and contiguous markets. They're one of the leaders in pharmacy."[35]

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[29] https://www.gianteagle.com/about-us/our-history (last accessed May 3, 2019).
[30] https://www.gianteagle.com/about-us/our-history (last accessed May 3, 2019).
[31] https://www.gianteagle.com/about-us/press-room (last accessed May 3, 2019).
[32] "Weekly Rx Volume by store (A1366710).xlsx".
[33] DSN's 2019 Retail Pacesetters Report (May 7, 2019), *available at* https://www.drugstorenews.com/retail-news/dsns-2019-retail-pacesetters-report/ (last accessed May 8, 2019).
[34] https://www.riteaid.com/about-us/our-story (last accessed May 8, 2019).
[35] Hamstra, M. 2019: Retail Pacesetters: Giant Eagle Offers Value in Food, Fuel and Pharmacy (May 7, 2019), *available at* https://www.drugstorenews.com/retail-news/2019-retail-pacesetters-giant-eagle-offers-value-in-food-fuel-and-pharmacy/ (last accessed May 8, 2019).

B. Giant Eagle Pharmacy

52. Giant Eagle owns and operates 227 pharmacies in five states: Pennsylvania, Ohio, West Virginia, Maryland and Indiana. Of the 227 pharmacies, 27 pharmacies are in Cuyahoga County and 13 pharmacies in Summit County. Giant Eagle's pharmacy business is comprehensive and includes a well-developed specialty pharmacy operation for patients with complex therapy needs, along with an extensive prescription delivery program and a dedicated pharmacy mobile application to drive awareness, therapy compliance and patient education.

53. Giant Eagle Pharmacy experienced rapid growth beginning in 2008 and peaking in 2012 after new store growth slowed. Consistent with the decline in new construction, the pharmacy business began experiencing a decrease in annual prescription volume, compounded by 90-day fills, mandatory mail order and insurance exclusivity that affected many other pharmacy organizations.

C. Customer Demographics in Cuyahoga County and Summit County

54. In 2017, Cuyahoga County, OH had a population of 1.25M people with a median age of 40 and a median household income of approximately $47,000, which is lower than the national average. The population is 59% Caucasian, 29% Black or African American, and 6% Hispanic or Latino.[36]

55. The largest industry in Cuyahoga County is health care and social assistance. Registered nurses, health technologists and health technicians are among the most common jobs held by residents. In addition, Cuyahoga County has an unusually high number of physicians and surgeons compared to other counties.[37] Much of this is due to the abundance of health care offerings, including the renowned Cleveland Clinic Health System and University Hospitals

[36] https://datausa.io/profile/geo/cuyahoga-county-oh/ (last accessed May 3, 2019).
[37] https://datausa.io/profile/geo/cuyahoga-county-oh/#economy (last accessed May 3, 2019).

Health System. There are 22 registered hospitals, 97 nursing homes, 81 licensed residential care facilities and other supportive services for follow-up and routine care of the patient in this county.[38]

56. Bordering Cuyahoga County, Summit County, OH shares similar resident demographics with a population of 541k people with a median age of 41 and a median household income of approximately $55,000, which is lower than the national average. The population is 77% Caucasian, 15% Black or African American, and 4% Hispanic or Latino.[39]

57. Comparatively, health care and social assistance is one of the most common industries in Summit County, with an unusually high number of nurses.[40] There are 10 registered hospitals, 40 nursing homes and 39 licensed residential care facilities along with other health care related services.[41]

D. Role of Pharmacy within a Grocery Store

58. Co-locating a pharmacy within a grocery store makes good business sense and is an optimal partnership for customers looking to enhance their overall health, wellness and life expectancy. As food retailers strive to raise the profile of healthy options across their stores, they attract consumers that seek education, advice, products and services that naturally gravitate to its pharmacy out of convenience. Supermarket pharmacies have become an even more important resource to the growing percentage of consumers who are making healthier diets a key part of an overall health strategy aimed at treating and preventing chronic disease.

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[38] Ohio County Profiles: Cuyahoga County (2018). Prepared by the Office of Research, *available at* https://development.ohio.gov/files/research/C1019.pdf (last accessed May 7, 2019).
[39] https://datausa.io/profile/geo/summit-county-oh (last accessed May 3, 2019).
[40] https://datausa.io/profile/geo/summit-county-oh (last accessed May 3, 2019).
[41] Ohio County Profiles: Summit County (2018). Prepared by the Office of Research, *available at* https://development.ohio.gov/files/research/C1078.pdf (last accessed May 7, 2019).

59. As evidence to its commitment to health and wellness, Giant Eagle offers tremendous resources beyond traditional prescription filling to assist their customers in leading healthy lives, including vaccine administration and community advocacy, glucose monitoring programs, blood pressure monitoring and tracking, specialty pharmacy, contact lenses, in-store dieticians and much more[42]. The Giant Eagle wellness team assists patients in managing complex treatment plans for co-morbidities such as heart disease, diabetes, gastroesophageal reflux disease (GERD), gout, hypo/hyperthyroidism, food allergies, Celiac disease, obesity and malnutrition.[43]

60. Understanding that food and health are symbiotic, Giant Eagle employs a team of registered dieticians to personalize a patient's diet plans based on their specific and unique calorie and nutrition needs. They offer meal planning assistance, recipes, and nutrition education for increasing or decreasing calories or weight, preserve and increasing immune function and label reading through brochures, in-store events, nutrition-based store tours and one-on-one counseling.[44]

E. Separate and Distinct Leadership and Infrastructure

61. Because Giant Eagle recognizes the importance of pharmacy and the opportunities and challenges of this highly regulated industry, the organization operates a pharmacy infrastructure that is separate from its main grocery business in order to focus on patient care, prescription delivery and costs, supply chain, regulatory compliance, training and other health care related issues.

[42] https://www.gianteagle.com/about-us/our-history (last accessed May 3, 2019).
[43] https://specialtyrx.gianteagle.com/AboutUs/DietitianServices (last accessed, May 8, 2019).
[44] https://specialtyrx.gianteagle.com/AboutUs/DietitianServices (last accessed, May 8, 2019).

62. Within the corporate office, the Giant Eagle team consists of various levels of executive, director, and management roles committed to the successful operation of the business, compliance with all federal and state regulations, and care of their patients. For example, corporate buyers utilize a computerized inventory management system (IMS) to control and closely monitor all orders at the warehouse. This includes incoming and outgoing orders between the stores and the distribution center and the incoming orders from manufacturers to the distribution center.

63. The corporate office has a dedicated human resources department to ensure all employees are properly trained and licensed, including regular training experiences to update and improve knowledge on controlled substance diversion. Human resource specialists teach about compliance and operational related practices using a variety of modalities including in-person training, computer-based learning and written education. The State of Ohio Board of Pharmacy, and other governing boards, mandate annual compliance training for all staff involved with controlled substances that educates and tests the employees' knowledge on how best to identify and protect against theft and diversion.

64. Giant Eagle maintains a robust pharmacy security and loss prevention department which includes experienced investigators with substantial law enforcement backgrounds. Among other responsibilities, inspectors visit stores routinely, educate pharmacy employees on theft and diversion deterrents and work with local police, DEA and Boards of Pharmacy on community advocacy and oversight.

65. Pharmacy District Leaders (PDLs) are responsible for oversight of the pharmacies, inspecting all pharmacy operations, enforcing company-wide policies and procedures, and ensuring compliance with state and federal regulations. They perform quarterly

internal audits to test and approve compliance with all policies and procedures. Because most or all of the PDLs are also pharmacists, they help train employees on both corporate and pharmacy specific practices. PDLs also work with law enforcement and the Boards of Pharmacy to help deter diversion and prosecute criminals.[45]

F. Giant Eagle Pharmacy Distribution Capabilities: HBC & GERx

66. As part of its commitment to patient care, Giant Eagle operated HBC Service Company, which served as a limited supply pharmacy drug warehouse for its pharmacies from November 2009 until January of 2016, carrying only Legend drugs and Schedules III-V Controlled Substances. In January of 2016, Giant Eagle stopped using HBC for pharmaceutical supply and opened a new warehouse, the Giant Eagle Rx Distribution Center (GERx), transitioning their pharmacy distribution business into this new, state-of-the art facility. Both HBC and GERx are Giant Eagle's captive self-distribution logistics and supply chain network dedicated to servicing only Giant Eagle pharmacies and no other third parties including internet pharmacies

67. Like most pharmacies with self-distribution capabilities, the drug warehouse and its distribution capabilities are a strategic asset and advantage for the organization that improves visibility, tracking and overall management of drug inventory. Due to the industry's volatile pricing and supply chain challenges, Giant Eagle can better manage interruptions in service, thereby protecting their patients and the cost of their medications.

68. Before opening GERx, Giant Eagle electively sought approval from the National Association of Boards of Pharmacy (NABP) for VAWD certification. The Verified-Accredited Wholesale Distributors (VAWD) accreditation is for facilities engaged in the act of wholesale

[45] Deposition of George Chunderlik, dated January 16, 2019, pp. 268-70.

drug distribution. To become VAWD-accredited, facilities must undergo a criteria of compliance review, which includes a rigorous inspection of the operating policies and procedures, licensure verification, a survey of the facility's operations, and screening through the NABP Clearinghouse. According to NABP, "VAWD accreditation helps ensure that the wholesale distribution facility operates legitimately, is licensed in good standing, and is employing security and best practices for safely distributing prescriptions drugs", which helps protect the public from drugs that have been contaminated, diverted, or counterfeited.[46]

69. After substantial investment in time and resources, VAWD accreditation efforts were suspended for HBC due to the imminent closure of the facility. The work was redirected to GERx and accreditation achieved.

1. Market Share of Prescription Opioids Distributed by HBC/GERx

70. HBC distributed only Schedule III prescription opioids, solely to Giant Eagle retail pharmacies, and only for a short duration within the relevant time period. HBC was licensed to distribute Legend drugs and Schedule III through V controlled substances. The company distributed hydrocodone combination products (HCPs) between November 12, 2009, and September 30, 2014, prior to the DEA action to reclassify HCPs from Schedule III to the more-restrictive Schedule II in October of 2014.

71. GERx is licensed for and distributes all drugs for retail sale, including Schedule II prescription opioids, solely to Giant Eagle retail pharmacies, beginning in March 2016 through current day.

[46] VAWD: Contributing to a Safe Wholesale Distribution and Supply (2019). National Association of Boards of Pharmacy, *available at* https://nabp.pharmacy/programs/vawd/ (last accessed May 5, 2019).

72. HBC/GERx distributed a very small fraction of all prescription opioids dispensed in Cuyahoga and Summit counties during the relevant time period. Between 1996 and 2018, the amount of prescription opioids distributed by HBC and GERx in the two counties was [redacted]% on an MME basis and [redacted]% on a dosage unit basis. For the period 2006 to 2014, HBC's share of opioids distributed in the two counties was [redacted]% on an MME basis. See Exhibit D.

73. HBC/GERx distributed only a small proportion of prescription opioids dispensed in Cuyahoga and Summit counties on a per capita basis during the relevant time period. See Exhibit E and Exhibit F. These data also show no shipments of prescription opioids by HBC or GERx between October 2014 and March 2016.

74. The volume of HCPs distributed by HBC/GERx generally tracked below quotas set by the DEA. See Exhibit G. The data shows that distribution of hydrocodone combination products from HBC was below the expected amount on an MME basis between 2012 and 2017 when indexed to the DEA quota for hydrocodone products starting in 2010. The data also shows no shipments of any HCPs from HBC or GERx during 2015.

75. Based on my analysis of the data presented above, I conclude that HBC/GERx account for a very small share of the total market for the distribution of prescription opioids in Summit and Cuyahoga counties, and that the share of HCPs distributed by HBC and GERx declined over time relative to production quotas for hydrocodone established by the DEA.

2. Dispensing of Controlled Substances by Giant Eagle Pharmacies

76. Giant Eagle pharmacies dispense a wide range of prescription drugs, typical of legitimate retail pharmacies, including both controlled substances and other non-controlled prescription drugs. The ratio of controlled substance prescriptions to total prescriptions dispensed, for all Giant Eagle pharmacies in Summit and Cuyahoga counties during the relevant time period was less than 10%. See Exhibit H. Notably, this data contains all controlled

substance transactions, concluding that the ratio of only HCP to total prescriptions is substantially less than 10%. And, although there is no precise threshold for the proportion of controlled substance prescriptions relative to other (non-controlled) prescription drugs above which it would be standard industry practice to investigate distributor transactions, a ratio of approximately 20% controlled to 80% non-controlled prescriptions is commonly accepted.[47]

77. The ratio of controlled substance prescriptions to total prescriptions dispensed by Giant Eagle pharmacies declined over the relevant time period, from a high of approximately 12% in 2009 to less than 8% in 2018. See Exhibit I.

78. In 2014, across regions where Giant Eagle has a presence (e.g., Western Pennsylvania and parts of Ohio, West Virginia, Maryland, and Indiana), the stores' market share for prescriptions for at-issue hydrocodone and oxycodone products was 18.60%, compared with a market share of 24.41% for non-controlled prescription drugs dispensed by Giant Eagle pharmacies. See Exhibit J. In 2015, the Giant Eagle share of the market in the same regions for these at-issue controlled substances declined to 16.99%, compared with 23.35% for non-controlled prescription drugs.

79. Based on the data presented above, I conclude that Giant Eagle pharmacies in Summit and Cuyahoga counties dispense a wide range of prescription drugs that meet the healthcare needs of Summit and Cuyahoga counties, dispensing a smaller share of prescription opioids compared to other retail pharmacies and filling a modest number of prescriptions for controlled substances that is well below the level expected for legitimate retail pharmacies. During the relevant time period, the share of prescriptions for controlled substances dispensed by

[47] Deposition of Kyle J. Wright, February 28, 2019, at 260:1-22.

Giant Eagle pharmacies declined steadily, indicating that the pharmacies were exercising effective controls to prevent diversion of prescription opioids.

80. Considering the relative size of HBC/GERx discussed in section III.F.1 above and the smaller share of prescription opioids dispensed by Giant Eagle pharmacies discussed in ¶ 79, HBC and GERx were de minimis distributors of at-issue opioids in Cuyahoga and Summit Counties.

IV. RETAIL DRUG DISTRIBUTION AND INVENTORY MANAGEMENT

A. Prescription Filling Process

81. To understand how prescription drugs are prescribed and dispensed, it is important to understand how the process is influenced by several decision makers, including prescribers, pharmacists, insurers, and patients, as well as the regulatory and institutional features of the marketplace that influence which drugs are prescribed and dispensed.

a) The Role of the Prescriber

82. The first step in the process occurs when a prescriber writes a prescription for a patient. In general, a patient seeks medical treatment, the prescriber examines the patient, reviews their medical history, performs any necessary tests, and then uses their extensive knowledge and experience to determine the diagnosis. The prescriber will then develop a specific treatment plan, which often requires one or more prescription drugs.

83. When a prescriber writes a prescription for a patient, the prescription specifies a certain drug molecule. The specific drug may be designated using the marketed brand name (such as Norco™) or by using the "generic" or active ingredient name (such as Hydrocodone/APAP). The prescription also will specify a certain dosage form (e.g., tablet, capsule, elixir), the strength (e.g., 5 mg vs. 10 mg), and specific directions for use (e.g., take once or two tablets by mouth every four to six hours as needed for pain).

84. Prior to prescribing a controlled substance for a patient, a doctor should access a prescription drug monitoring program (PDMP), which digitally stores controlled substance dispensing information and makes the information available to prescribers, pharmacies and law enforcement officials. Although PDMPs are designed to curb opioid overprescribing, prescriber registration is approximately 35% and regular utilization is low.[48]

85. Consequently, 22 of the 49 states with PDMPs now legally mandate prescribers to query the system before writing for controlled substances with recognized potential for abuse or dependence[49]. These requirements face pushback from prescribers, many of whom consider them to be burdensome incursions into clinical practice and unnecessary. In fact, Thomas Patterson, Acting Administrator of the DEA, in a hearing dated May 8, 2018, entitled, "Challenges and Solutions in the Opioid Crisis" before the Committee of the Judiciary House of Representatives, admits that the overwhelming majority of prescribers care for their patients and order legitimate prescriptions. He explained that 99.9% of doctors are trying to treat their patients responsibly, leaving the remaining one-tenth of one percent of prescribers responsible for prescription-based opioid related diversion.[50]

86. Conversely, proponents argue that required PDMP consultation is necessary to change prescribing behavior, citing evidence from states that have deployed mandates to demonstrate their potential to reduce opioid abuse.

87. Established in 2006, the State of Ohio Board of Pharmacy created the Ohio Automated Rx Reporting System ("OARRS"). OARRS collects information on all outpatient

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[48] Haffajee, R. L., Jena, A. B., & Weiner, S. G. (2015). Mandatory use of prescription drug monitoring programs. *JAMA*, *313*(9), 891–892. doi:10.1001/jama.2014.18514, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4465450/ (last accessed May 5, 2019).

[49] Haffajee, R. L., Jena, A. B., & Weiner, S. G. (2015). Mandatory use of prescription drug monitoring programs. *JAMA*, *313*(9), 891–892. doi:10.1001/jama.2014.18514, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4465450/ (last accessed May 5, 2019).

[50] Deposition of Thomas Provoznik, dated April 17-18, 2010, pp. 436-441.

prescriptions for controlled substances dispensed by Ohio licensed pharmacies. This data is reported every 24 hours and is maintained in a secure database. Drug wholesalers are also required to submit information monthly on all controlled substances sold to an Ohio licensed pharmacy or prescriber.

88. Reportedly, OARRS is a tool that can be used to address prescription drug diversion and abuse. It serves multiple functions, including: patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool. As the only statewide electronic database that stores all controlled substance dispensing and personal information, OARRS helps prescribers and pharmacists avoid potentially life-threatening drug interactions, as well as, identify individuals fraudulently obtaining controlled substances from multiple health care providers, a practice commonly referred to as "doctor shopping." It can also be used by professional licensing boards to identify or investigate clinicians with patterns of inappropriate prescribing and dispensing, and to assist law enforcement in cases of controlled substance diversion.[51]

89. Doctors in Ohio are required to consult OARRS before prescribing a new opioid for a patient and then only every 90 days if continuing therapy. There are also exceptions to the mandate, including:

- short duration prescription of seven days or less
- prescriptions for terminally ill patients
- prescriptions issued or administered at hospitals and long-term care facilities
- cancer treatment

[51] What is OARRS? State of Ohio Board of Pharmacy, *available at* https://www.ohiopmp.gov/About.aspx (last accessed May 5, 2019).

- treatment of acute pain from surgical or other related invasive procedures
- if the system is inaccessible[52]

90. After being seen by the doctor, the patient will then have the prescription filled, most often at a retail pharmacy, which includes independent pharmacies, chain drug stores, grocery stores with in-house pharmacies, and mass merchants. Patients may also receive their prescriptions through a mail order pharmacy, a hospital outpatient pharmacy, a long-term care pharmacy, a clinic, or a prescriber who dispenses prescriptions.

91. There are four general ways in which a prescription gets communicated from a prescriber to the pharmacy where the patient will have it filled: (1) the prescriber may write or print the prescription on paper, sign it, and hand it to the patient, who delivers it to the pharmacy; (2) the prescriber's office may transmit the prescription electronically to the pharmacy, such as by e-mail; (3) the prescription may be faxed from the prescriber's office to the pharmacy; or (4) the prescriber's office may call the pharmacy. The first two options are the mostly widely used, especially following the introduction of electronic prescriptions or "e-scripts" around 2004 and legalized nationwide in 2007.

92. The DEA did not approve electronic prescribing for CII substances until 2010. Unfortunately, due to process complexity and limitations, many prescribers cannot utilize the e-script option for CII substances, therefore most of these prescriptions are still on paper and delivered by the patient to the pharmacy.

b) Prescription Review and Entry

[52] When Are Prescribers Required to Use Prescription Drug Monitoring Programs? (2018). The PEW Charitable Trusts, *available at* https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs (last accessed, May 5, 2019).

93. All pharmacies use a prescription management system ("PMS") to assist them in the prescription-filling process and to prompt specific interventions for operational and legal compliance. Regardless of the specific software application used to run a PMS, most of the functionality is consistent. This software can be, and often is, customized by individual users.

94. During the prescription filling process, the pharmacist will assess the prescriber information and determine if and how a prescription is dispensed per the prescription instructions. Pharmacies play an integral role in determining the legitimacy of prescriptions. Because of safety and compliance, theft and diversion concerns surrounding controlled substances, these prescriptions are scrutinized with a more focused lens. According to the DEA, "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[53] The regulation clearly states that the prescribing practitioner has full responsibility for proper prescribing and dispensing of controlled substances. The regulation also indicates a corresponding responsibility of the pharmacist who fills the prescription. Controlled substance prescriptions have different regulations than standard legend drugs and the pharmacist will ensure the prescribed information is accurate before continuing the process.

95. In addition to assessing the accuracy of the prescribed information, the pharmacist will reference any available and applicable state monitoring system, such as the Ohio Automated Rx Reporting System ("OARRS"). These systems are designed to monitor controlled substance prescriptions and can give a prescriber and pharmacist critical information regarding a patient's medication history of controlled substance usage.

[53] 21 C.F.R. § 1306.04.

96. It is not the role or obligation of the pharmacist to challenge a doctor's diagnosis or treatment plan, however, if there are questions regarding the prescription, a pharmacist will communicate with the prescriber regarding a prescription to discuss the drug, strength, dose or frequency of utilization for a specific patient and discuss the appropriate course of action as part of their "corresponding obligation". A pharmacist may not alter a prescriber's treatment regimen without prescriber's consent. However, a pharmacist may, at any time, exercise their professional judgement and refuse to fill a prescription that appears fraudulent, outside the scope of practice or not in accordance with standard treatment guidelines.

97. Once the prescribed information is evaluated, pharmacies will dispense the most cost-effective drug based on the prescription and state-specific drug-selection and substitution laws. Most pharmacies will dispense an FDA-approved, A-rated generic drug, rather than the brand name drug prescribed by the physician, if the following criteria are met: (a) an FDA-approved, A-rated generic drug is available for substitution; (b) the pharmacy has the drug in stock; (c) the patient's insurance company approves reimbursement for the substituted drug; and (d) the prescriber has not taken any step to prevent substitution, such as prescribing the brand name drug *and* specifying that it must be dispensed as written (DAW).

c) Insurance Coverage and Adjudication

98. Adding another level of control, checks and balances, health insurance organizations orchestrate an elaborate review and approval process prior to a prescription being dispensed. Over 90% of all prescriptions are filed and adjudicated with third-party insurance companies.[54] Health insurers, including private companies as well as Medicare, Medicaid, and

[54] "Why Retail Pharmacies Still Overcharge Uninsured Patients," Drug Channels (Apr. 19, 2018), *available at* https://www.drugchannels.net/2018/04/why-retail-pharmacies-still-overcharge.html (last accessed May 3, 2019).

the state and federal agencies that administer these programs, use various tools to help steer patients towards medically appropriate, cost-effective medicines. In many cases, a pharmacy benefit manager (PBM) is responsible for designing and executing a cost-effective system for their insurance company clients. A PBM is essentially a broker between payers representing patients, drug manufacturers, and retailers, designing and implementing drug formularies based on medical need and financial performance. PBMs will reject prescriptions and deny reimbursement on medications that do not meet the specifications of the plan, leaving the patient to pay cash for therapy or do without medication.

99. Because a PBM obtains information for every prescription adjudicated for payment, these organizations have the ability to aggregate all prescription information and dispensing for an individual patient. Whereas, a single pharmacy only has visibility to those prescriptions filled at the specific pharmacy. PBMs play a vital role in assisting pharmacists with potential drug-drug interactions that are not apparent if a patient uses more than one pharmacy. The PBMs also assess drug utilization and will prevent prescriptions from coverage based on excessive quantities, duration, or frequent consumption.

d) Finalizing the Prescription – Counseling the Patient

100. After the prescription is entered into the computer, checked for accuracy, drug interactions, drug utilization and adjudicated by insurance, if available, a pharmacy technician will count and label the prescription.

101. A pharmacist will then double check the label information and ensure that the contents of the bottle match the prescribed product. In addition, the pharmacist will also repeat review of the patient's drug history and ensure any potential drug-drug interactions or drug-disease interactions have been resolved before completing the transaction with the patient.

102. A pharmacist, or pharmacist's designee must offer to provide counseling on each prescription dispensed. A typical discussion between pharmacist and patient or the patient's caregiver depends on the medication and includes the name, dose and strength of the medication, how to take the drug as prescribed, any expected side effects and management techniques, refill information, and proper storage and disposal. Pharmacists also supplement with printed drug information that is automatically printed by their PMS with each new prescription. An example of the patient information for HCP is provided as Exhibit K[55] and the FDA approved Medication Guide for Norco™ as Exhibit L.[56]

B. Inventory Management Systems and Controls

a) Product Replenishment

103. Inventory is the largest expense for any pharmacy and priority efforts are expended to manage and retain the lowest cost structure possible while maintaining product supply for optimum patient care.

104. In general, the pharmacy PMS manages the inventory needs for a pharmacy. As a prescription is dispensed, the PMS will decrement the available inventory and automatically reorder the product according to established patterns of utilization. The goal is to maintain an adequate, but not excessive, level of inventory to fulfill patient needs. In my experience, most pharmacies will carry only a few days of inventory on the shelf depending on the order cycles from their distributor and the availability of product supply. Replenishment orders are electronically transmitted to the pharmacy distributor and it is common for the orders to be received the next business day.

[55] Hydrocodone/Acetaminophen Patient Information, *available at* https://online.epocrates.com (last accessed May 5, 2019).
[56] Norco Medication Guide (2016), *available at* http://online.lexi.com/lco/medguides/656037.pdf (last accessed May 5, 2019).

105. If products are in short supply or anticipated to be in short supply, pharmacists will order these items outside normal patterns and at larger than customary quantities. Based on my experience, drug shortages for many opioids occur at the end of the calendar year due to expired quotas and limitations in manufacturing imposed by the DEA and will continue into the first quarter when production resumes. Therefore, the data may show an increase in order quantities in anticipation of these shortages for the end of the calendar year as pharmacists prepare for the event to have enough product to take care of their patients.

106. The US Attorney General (AG) is charged with the statutory authority to establish production quotas, which was then delegated to the DEA. Specifically, 21 USC § 826 requires the AG to set a limited production quota for Schedule II controlled substances to provide for the estimated needs of the country. It is a balancing act that is accomplished through a scientific and mathematical exercise conducted by DEA scientists.[57] The procedures and requirements employed to establish quota are found in 21 CFR §1303.

107. Controlled substance quotas are established annually and updated once during the calendar year. An aggregate production quota is established by the DEA for each basic class of drug like hydrocodone, oxycodone, or oxymorphone and calculated from estimates supplied by manufacturers based on anticipated business activities for the coming year. These quotas determine how much Active Pharmaceutical Ingredient (API) that each manufacturer can utilize for drug production in a given year. The CSA specifically prohibits the DEA from establishing production quotas in terms of individual pharmaceutical dosage forms, and once a quota is issued, the DEA has no authority to require a manufacturer to produce a specific drug, dosage,

[57] Albert, E. Debunking the Myths of Controlled Substance Quotas (June 1, 2018). *Pharmacy Times*, *available at* https://www.pharmacytimes.com/publications/career/2018/careersspring2018/debunking-the-myths-of-controlled-substance-quotas (last accessed May 6, 2019).

bottle size or route of administration. [58] Admittedly, the DEA recognizes the faults with setting quotas and understands that manufacturers' business practices may lead to a shortage of controlled substances.[59]

108. In addition to the inventory ordering process above, only Schedule II Controlled Substances require special review and acknowledgment. To order and receive CII drugs, a pharmacist must complete a DEA Form 222. This official form is required for every distribution, purchase or transfer of a Schedule II controlled substance. When ordering CII medications, the number of packages, size of the package and name of the item must be filled out completely on the form. Each form must be reviewed, signed and dated by an authorized individual with "power of attorney" to execute such official DEA forms and this authority typically resides with the pharmacist. The pharmacy keeps a copy of the order form for their records and sends the original to the distributor for fulfillment.

109. Any sign of alteration on a DEA order form may cause a distributor to refuse the entire order. The typical turnaround time from submission to delivery for an order using the DEA Form 222 is generally one to eight days depending on method of delivery, accuracy of the form, weather, quotas, and lack of inventory.[60]

110. Responding to industry needs and enabling advancements in technology, the DEA approved electronic ordering of controlled substances by electronically completing the Controlled Substance Ordering System (CSOS). The CSOS allows for secure electronic transmission of controlled substance orders without supporting paper documentation.

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[58] 21 U.S. Code § 826 - Production quotas for controlled substances. Legal Information Institute, *available at* https://www.law.cornell.edu/uscode/text/21/826 (last accessed May 5, 2019).
[59] Quotas (2018). Drug Enforcement Administration, Department of Justice, *available at* https://www.deadiversion.usdoj.gov/fed_regs/quotas/2018/fr1228 htm (last accessed May 6, 2019).
[60] Controlled Substances Ordering System. Drug Enforcement Administration, *available at* https://www.deaecom.gov/overview.pdf (last accessed May 5, 2019).

Pharmacists must obtain a digital certificate for ordering, which may only be granted by DEA registrants and individuals who are given power of attorney by registrants. Just like the Form 222, the pharmacist must review and approve accuracy all CII orders before submitting the order to the distributor.

b) The Role of the Distributor

111. Pharmaceutical distributors sustain and manage a complex web of supply chain, serving as an important link in the healthcare system by connecting manufacturers' products with pharmacies that can dispense them to patients. Distributors are logistics experts that transport products safely, securely, and efficiently, often operating 24 hours per day to ensure access to prescription medications.

112. In general, pharmaceutical distributors service two clients, the manufacturers and the pharmacies. The manufacturers work with wholesalers to distribute their drugs to more than 67,000 pharmacies in the United States[61]. And, the pharmacies rely on wholesalers for access to and delivery of thousands of drugs and other health related items. Besides contracting for drug distribution, distributors also provide a variety of other functions depending on and customized for the needs of the clients.

113. Federal law regulates wholesale drug distributors through implementation of the Prescription Drug Marketing Act of 1987[62]. Wholesalers are also regulated by individual states through licensing and various state-specific regulations. The State of Ohio requires licensure in the state upon verified eligibility and by the State of Ohio Board of Pharmacy[63] In addition, all

[61] National Pharmacy Market Summary. SK&A (March 2010), *available at* http://www.skainfo.com/index.php (last accessed May 5, 2019).
[62] 21 C.F.R. § 205.
[63] 47 O.R.C § 4729.51-53.

drug distributors must register with the DEA and comply with all regulations outlined in the Controlled Substances Act.[64]

114. Some organizations, like Giant Eagle, own and operate pharmacies and a dedicated distributor as a strategic advantage over other non-warehousing pharmacy chains. This type of captive self-distribution creates a closed loop of secure inventory management that improves drug forecasting, visibility, price protections and product access for improved patient care. Self-distributors, unlike the traditional wholesaler model, maintain control of the prescription product even after it ships to the stores, further eliminating risk of diversion. In addition, the order can be recalled if the need ever arises.

c) Receiving an Order from the Distributor

115. When a pharmacy receives an order from the distributor, products are divided according to regulations. Legend (non-controlled substance) products are separated from CIII-V and CII products are in their own box and each has a separate invoice. All the boxes come sealed from the distributor and the orders signed and confirmed by the receiving pharmacist. Pharmacists open each package, confirm the contents match what was ordered, enter the products into the PMS inventory and place them on the drug shelves or in the secured cabinet or safe.

116. According to the CSA, Controlled Substance audits and inventories must be completed once every two years. CIII-CV volume can be estimated and CII products require an exact count or measurement.[65] Intensifying the level of record keeping, the State of Ohio Board of Pharmacy requires a controlled substance inventory every year and like the Federal regulation, the CIII-CV products can be estimated and CII products require an exact count or

[64] 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.
[65] 21 C.F.R. § 1304.11

measurement.[66] In reality, most pharmacies take inventory of controlled substances on a more frequent basis; many of them confirm the accuracy of CII inventory counts with each prescription dispensed.

C. Corporate Controls on Responsible Product Purchasing

117. Within large retail pharmacy organizations, corporate buyers design a preferred drug formulary of the drugs they will stock based on insurance requirements, quality, cost, and supply chain competencies. Pharmacies must carry the drugs that their patients' insurance companies require to retain business. Pharmacists may influence prescribing behaviors by communicating insurance coverage preferences and limitations to doctors in order to facilitate efficiencies with patient care.

118. When making buying decisions regarding FDA-approved generic drugs, buyers usually select one manufacturer per drug molecule to aggregate volume and receive the best costs. Depending on the quantity of drug needed, buyers may also contract with multiple manufacturers to reduce supply chain risks, but a single retail location will normally carry only one manufacturer of a specific drug. As market shifts occur, buyers will adjust their preferred formulary and manufacturers as changes in drug cost and availability occur.

119. With independent pharmacists and small chains, most purchasing decisions are delegated to the store level. The pharmacist will look at what drugs are available from their respective wholesaler and the cost of each drug before making their purchasing decisions.

120. Corporate buyers develop budgets and forecasts for drug utilization by category to ensure financial management of the business and to communicate with manufacturers and distributors about the required inventory needs based on current prescription dispensing. Buyers

[66] Ohio Administrative Code 4729-9-14.

watch trends in the industry and within their area of responsibility and will adjust forecasts as the needs of the business change. Any unexpected changes are researched thoroughly to either take advantage of the upsides or mitigate the opportunities of any risk that may be presented. Unexpected changes in inventory levels or orders for controlled substances are researched thoroughly as part of theft and diversion controls.

121. At Giant Eagle, corporate buyers utilize a computerized inventory management system to control and closely monitor all orders at the warehouse. This includes incoming and outgoing orders between the stores and the distribution center and the incoming orders from manufacturers to the distribution center.

V. GIANT EAGLE'S COMPLIANCE WITH CONTROLLED SUBSTANCES ACT

A. CSA Obligations

122. The Controlled Substances Act of 1970 is a statute that establishes US drug policy and creates a system for the legitimate manufacturing, distribution, and prescribing/dispensing of controlled substances. Each registrant within this "closed system of distribution" has defined privileges and responsibilities in which they must operate. Once the prescription is dispensed and leaves the control of the pharmacy, the patient assumes responsibility for using the drug as prescribed, keeping it safe and disposing of unused portions appropriately.

123. With a concentration on delivering exceptional patient care, Giant Eagle fulfills its obligations to and is in compliance with the provisions outlined in the Controlled Substances Act. Giant Eagle maintains an integrated infrastructure of interdependencies beginning with the pharmacy, through the distribution center and extending into oversight from leadership in the corporate office consistent with industry standards. Giant Eagle is highly focused on preventing theft and diversion by, in many cases, exceeding expectations related to federal and state guidelines. The DEA and State Boards of Pharmacy perform comprehensive inspections and

audits of Giant Eagle pharmacies and HBC/GERx to test and approve sufficient controls are in place and effective. Giant Eagle and the DEA maintain a cooperative and engaging relationship and the DEA has never sanctioned Giant Eagle for failure to comply with any regulation or found them deficient in any controls.[67].

124. Summarizing the CSA, 21 CFR §1301.71, it states that, "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." The statute continues with, "…the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion" and that, "Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant."[68]

B. Physical Security and Controls

125. 21 CFR §1301.72 details the physical security controls required for CII substances and CIII-CV. In accordance with the regulations, both HBC and GERx meet or exceed each of these requirements. For example:

- All controlled substances are housed in a steel cage or vault and no cross-docking allowed
- Security cameras, video surveillance and guards monitor the facilities
- For outbound product, inventory is counted before the business day starts, when it ends and prior to scheduled breaks
- For inbound product, inventory is counted at point of receipt and reserves slots verified

[67] Deposition of George Chunderlik, dated January 16, 2019, p. 266.
[68] 21 CFR §1301.71.

- Limited personnel access to controlled substances, with a maximum of two employees at a single time for order fulfillment.
- Vocollect software application and hardware comprised of a headset and wearable scanner to communicate inventory location for accuracy of order fulfillment and replenishment
- Manhattan software application to manage incoming and outgoing orders, cycle counts, inventory reconciliation, audits, etc.
- Order specialists to monitor store orders for accuracy and appropriateness and any deviations from typical ordering patterns
- Beginning in 2013, daily threshold reports, redundant threshold systems and additional software applications for order monitoring.[69]

126. Similarly, each individual Giant Eagle Pharmacy has security controls that meet or exceed each of the requirements of the Controlled Substances Act and those of the State of Ohio Board of Pharmacy through official written policies and procedures and unwritten standards of practice within the pharmacy industry. For example:

- Redundant surveillance and security systems covering the entire building and specific to the pharmacy
- Highly educated, licensed and trained pharmacists and pharmacy technicians
- Written policies and procedures, including Controlled Substance Dispensing Guidelines
- PMS for inventory management and automatic replenishment ordering
- Limited legal authority for review of all controlled substances orders

[69] Deposition of Walter Wayne Durr, dated January 22, 2019, at pp.83-91.

- Inventory counts and back-counts with each prescription (CIIs) and monthly narcotic audit.
- CIIs kept isolated from other inventory in secured cabinet or locked safes with pharmacist-only access.[70]

C. Overview of Giant Eagle's Inventory Management, Replenishment Pathway and Controls

127. During each step in the pathway of drug replenishment, Giant Eagle is hyper-focused on preventing theft and diversion. They have evolved business practices over the years as technology enables more automation for previously manual processes.

128. Giant Eagle pharmacies play an integral role in preventing theft and diversion by scrutinizing every controlled substance prescription that is presented by the patient. Giant Eagle authored and distributed Giant Eagle's Controlled Substance Dispensing Guidelines to be retained in all stores in addition to the DEA Pharmacist Manual.[71] By confirming the legitimacy of the prescribed information, the pharmacist is ensuring that the product is not being dispensed inappropriately. After a prescription is filled in the PMS, inventory is automatically decremented to reflect current shelf stock. For CIIs, pharmacies manually count the inventory with each fill to ensure accurate on-hands and that on-hands match the inventory count in the PMS.

129. At the end of the day, the PMS will automatically generate a drug replenishment order based on the day's business and the need for product to fulfill future business. The pharmacist will review the controlled substances order for accuracy, electronically sign the order via legal authority and submit the order to the warehouse via CSOS.

[70] Deposition of George Chunderlik, dated January 16, 2019, pp, 263-264
[71] Deposition of George Chunderlik, dated January 16, 2019, p. 252.

130. Once received at the warehouse, the order is reviewed for accuracy. If issues are detected or questions raised, the order will be suspended until management finds a resolution. If no issues are detected, the order is filled and shipped to the store.

131. The pharmacist will then receive the replenishment order from the warehouse, confirm that all totes are sealed and sign for the delivery. With detail, the pharmacist will check the order for accuracy, scan each product to add inventory back into the PMS and finalize the order by signing the paperwork and filing according to state law. If any mistakes in shipment occurred, the pharmacist will promptly contact the distribution center and report the issue.

132. Captive self-distributors maintain control of the prescription product even after it ships to the stores, further eliminating risk of diversion. In addition, the order can be recalled if the need ever arises.

133. Like the pharmacies, the distribution center also has automated ordering and receiving processes. The inventory is automatically decremented with each bottle picked for a store. The warehouse counts, re-counts and audits inventory levels on a daily schedule, exceeding the legal requirements, to prevent theft and the opportunity for diversion.

134. Replenishing stock for the distribution center is managed by the corporate buyers. The buyers contract directly with the manufacturers to forecast business inventory needs, supply agreements, pricing, terms and conditions, etc. These forecasts are reviewed and updated regularly to ensure adequacy of supply at both the distribution center and the stores. Any unexpected deviations to inventory levels outside the forecast are immediately investigated. Manufacturers will also compare actual versus forecasted inventory to guarantee proper allocation of product to all of its customers. Due to the quota limitations imposed by the DEA, there is little tolerance for demand changes within the replenishment pathway.

135. By imposing tight management controls on inventory at the stores and at the distribution center, Giant Eagle exceeds legal requirements in many areas and maintains optimum levels of product to ensure patient care.

D. Suspicious Order Monitoring and Reporting

136. In addition to all other requirements of the Controlled Substances Act, CFR §1301.74 describes "other security controls" necessary for compliance, including the design and implementation of a Suspicious Order Monitoring (SOM) system. Overall, a distributor's SOM program has three requirements:

1) Design and operate a system to identify suspicious orders of controlled substances. Such orders are defined as those of a) unusual size, b) unusual frequency, and/or 3) deviate substantially from a normal pattern.
2) Inform the DEA Field Office when a suspicious order is confirmed
3) Confirmed suspicious orders must be held until it is determined that the order likely will not be diverted.[72]

137. The DEA is overly ambiguous on what a suspicious order monitoring (SOM) "system" entails and does not approve or otherwise endorse any specific system for reporting suspicious orders, accepting both manual and technology enabled programs for the safety of controlled substances as long as the policies and procedures meet the regulations.[73]

138. Giant Eagle complies with all regulations and actively maintains a complex SOM system of integrated controls that has been a part of their standard operating procedures for decades. Giant Eagle's system encompasses all safety controls, theft and diversion procedures,

[72] 21 CFR §1301.74.
[73] DEA Letters from J. Rannazzisi to All Registrants (dated September. 27, 2006, February 7, 2007, December 27, 2007 and June 12, 2012). MDLSBCDMDL00269687, MDLSBCDL00269685, MDLSBCDL00269683.

technology, training and executive leadership exclusively within Giant Eagle Pharmacy, HBC Service Company/GERx, and Giant Eagle's corporate office.

139. In order to fulfill the system obligations, the DEA has stated that distributors should engage in a "Know Your Customer" policy and take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and consequently, identify those transactions conducted by their customers that are suspicious in nature. [74] As noted by Plaintiff's expert, Seth B. Whitelaw, throughout his expert report, the concept of "Know Your Customer" is critical to a successful SOM system and that "knowing a pharmacy's product mix of controlled versus non-controlled prescriptions together with local data…" are important pieces of information for a customer profile.[75] In fact, the DEA makes, clear, the Know Your Customer requirement is the basis for determining whether a customer's purchases are to be considered legitimate or diversionary. Mr. Whitelaw goes on to admit, "However, it also is important to remember that knowing one's customer and making determinations of whether orders are suspicious or legitimate is not simply a scientific endeavor (e.g., just using thresholds and algorithms), but also is an art requiring training, experience, innate skepticism, and common sense."[76]

140. Because Giant Eagle operates a captive self-distributor, it is intimately aware of its "Customer" as the "Customer" is its own stores. Giant Eagle's corporate leadership routinely visits stores, ensuring compliance to policies and procedures, rules and regulations. In addition, corporate buyers run daily reports to understand the pharmacy's product mix. They are keenly aware of the quantity of controlled versus non-controlled prescriptions and exactly how much

[74] Knowing Your Customer/Suspicious Orders Reporting. DEA Diversion Control Division, *available at* https://www.deadiversion.usdoj.gov/chem_prog/susp htm (last accessed May 7, 2019).
[75] Expert Report of Dr. Seth B. Whitelaw, dated April 15, 2019, at 26:6.1.2.
[76] Expert Report of Dr. Seth B. Whitelaw, dated April 15, 2019, at 26:6.1.2.

product is flowing through the organization. In addition, Giant Eagle trusts the expertise of their pharmacists and pharmacy staff, appreciating their "training, experience, innate skepticism and common sense" that comes with the profession.

141. Giant Eagle has evolved their SOM system of integrated controls over the years as advancements were made in technology, physical infrastructures and general business practices. Although not required by law, in 2013, Giant Eagle initiated a monthly ordering threshold and daily reporting for controlled substances using nationwide averages to assist leadership in flagging orders that exceeded certain pre-determined parameters. The threshold system advanced to daily thresholds based on independent store dynamics.

142. The orders flagged by these reports do not definitively indicate a suspicious order, but rather, are used to identify certain stores and orders that need further investigation because the business exceeds that of other averages and norms by which the thresholds were established. Items which exceed the established threshold trigger are scrutinized and investigated by field level personnel to determine if the items need to be removed from the order and reported to the DEA.[77] Even after Giant Eagle implemented the threshold system, all flagged orders for controlled substances were cleared, validating that existing policies and procedures prevent theft and diversion.

143. Discovery shows that Giant Eagle's integrated system of safety and controls is designed to largely prevent suspicious orders. Orders flagged by the threshold systems were all traced back to legitimate prescriptions and growth in the pharmacy business. Due to the overlapping checks and balances of the system to date, Giant Eagle has uncovered only two orders of concern that meet the DEA definition of "suspicious" and both orders were resolved

[77] HBC_MDL00132616.

and managed according to state, federal, and corporate regulations and policies. It is not surprising, however, that the number of documented and reported situations is limited. As explained, Giant Eagle has a complex, integrated system of controls that is aimed at preventing THEFT AND DIVERSION BEFORE IT CAN BEGIN.

VI. DR. MCCANN'S FLAGGING METHODOLOGIES

A. Context for the Use of Threshold-Based Methods in Identifying Suspicious Orders

144. Giant Eagle's HBC and GERx distribute prescription drugs solely to Giant Eagle retail pharmacies that are owned, operated and managed by the same parent company, Giant Eagle, Inc. In my experience, shipments of controlled substances within divisions of the same company are subject to an inherently lower risk of diversion than transactions with external customers. Although monitoring and reporting of shipments of controlled substances between distribution centers and retail pharmacies within Giant Eagle are required by the Controlled Substances Act, the use of threshold-based methods (i.e., algorithms that apply historical or pre-set thresholds of order frequency, dosage, or other characteristics) to identify potentially suspicious orders from customers are not required by the Controlled Substances Act. Furthermore, such threshold-based methods are neither an effective nor a rational means to detect diversion of controlled substances for shipments between divisions of the same company. The DEA warns against registrants utilizing and relying on rigid formulas to identify suspicious orders. Only orders labeled and confirmed as "suspicious" by the registrant should be submitted to the DEA. Simply communicating "excessive purchases" do not comply with the requirement.[78]

[78] See DEA Letter from J. Rannazzisi to All Registrants, dated June 12, 2012. ABDCMDL00269683.

B. Dr. McCann's Dataset Is Flawed

145. The dataset Dr. McCann uses in his "Transaction Analysis"[79] for HBC contains errors. Specifically, his dataset contains 4,206 duplicate transactions. This is not an error in the HBC data production, but rather in Dr. McCann's use of the company's data. In addition to the fact that plaintiffs' expert's analysis should not contain data errors of his own creation, the duplicate data biases the results of his "transaction analyses." For the following stores, which are in Cuyahoga county and included in GE's Cuyahoga production and its Cleveland production, Dr. McCann's dataset includes duplicates of every transaction between March 2016 and May 2018: Parma, Cleveland, Brookpark, Lakewood, Middleburg Heights, Brooklyn, Garfield Heights, South Euclid, and Beachwood.

C. Dr. McCann's "Transaction Analysis" Is Flawed

146. Dr. McCann implemented "various approaches to identify transactions meeting specified criteria using the non-public ARCOS Data from 2006 to 2014, supplemented with Defendant transaction data."[80] He presents five different "approaches," which result in a large number of transactions between HBC and Giant Eagle pharmacies being "flagged."[81] Dr. McCann does not explain the basis for the approaches or what expertise he applied in developing these approaches. Furthermore, Dr. McCann does not express an opinion regarding the results or apply any expertise to the interpretation of the results. Rather, he states: "I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction."[82]

[79] McCann Report, §IX, pp. 56-81.
[80] McCann Report, p. 56.
[81] McCann Report, Tables 24-33.
[82] McCann Report, p. 56.

147. Dr. McCann's transaction analyses suffer from several common flaws. As I discussed above, one fatal flaw is that Dr. McCann's dataset contains glaring errors — thousands of duplicate transactions — that lead to spurious results. Yet another fatal flaw that spans his transactions analyses is that Dr. McCann is using unproven, nonstandard, unprincipled methodologies that are void of research and application of widely accepted professional principles. An additional fatal flaw, which illustrates that Dr. McCann's approaches are not based on professional pharmaceutical practices or theory, is the fact that his unit of measurement for transactions is at the level of the active pharmaceutical ingredient (API). In my experience, it is not appropriate to evaluate pharmaceutical distribution practices exclusively at level of APIs. The wide range of potential formulations and dosages for a given API can result in products with very different characteristics. For example, under Dr. McCann's API focused approaches, a dosage unit of 5 mg oxycodone and 325 mg of acetaminophen is equivalent to a dosage unit of 80 mg of oxycodone despite their different ingredients, degrees of potency and varying transactional volume. Finally, in all five of Dr. McCann's approaches, Dr. McCann flags all transactions subsequent to the first flagged transaction. This means that he automatically impugns all subsequent transactions without an analysis of the fundamental properties of the transactions, thereby abandoning whatever modicum of professional principle might have supported his approach.

148. As a consequence of this failure to base his evaluation of transactions on professional pharmaceutical practices, there is no legitimate basis for Dr. McCann's thresholds, which he relies on to determine whether transactions should be "flagged," and the product of his "transactions analysis" is spurious results that can only be interpreted by counsel for the plaintiffs. Dr. McCann does not rely on any healthcare or pharmacy expertise, in the

interpretation of the results. In the sections below, I describe additional flaws that are specific to one or more of the individual approaches he has proposed.

D. Maximum Monthly, Trailing Six-month Threshold

149. Dr. McCann describes his first transaction analysis approach using the following language: "I identify transactions that cause the number of dosage units [for a particular drug (e.g., hydrocodone)] shipped by a Distributor [e.g., HBC] to a Pharmacy [e.g., Giant Eagle pharmacy in Cuyahoga or Summit counties] in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months."[83] Dr. McCann does not explain why this is a reasonable approach and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management. In addition to all the systemic flaws in Dr. McCann's transaction analyses, a flaw specific to this six-month approach is that it cannot control for increased shipments of opioids because of growth in overall store business; this approach merely identifies stores that are growing in their order volume.

150. For a given distributor/pharmacy/drug combination in a given month, Dr. McCann calculates a pharmacy-specific threshold which is the maximum monthly total dosage units during the previous 6 months of transaction data. This pharmacy-specific threshold changes every month, reflecting the trailing 6-month period. If the store-specific maximum monthly dosage units are less than 1,000, Dr. McCann uses 1,000 dosage units as the threshold; in other words, in his 6-month trailing maximum approach, the store-specific monthly threshold for flagged transactions for any drug is always greater than or equal to 1,000 dosage units. In the

[83] McCann Report, p. 56.

case of HBC, the company started supplying Giant Eagle pharmacies with Schedule III opioids (HCP and codeine combination product) in November 2009; 38 of the 39 Giant Eagle pharmacies located in Cuyahoga and Summit counties were open in November 2009 and reported receiving a shipment of HCP on November 12 or 13, 2009.[84] The first month of HCP transactions Dr. McCann scrutinizes using the trailing 6 month maximum approach is May 2010, the seventh month after shipments of HCP commence. Under this approach, Dr. McCann flags HCP transactions between HBC and all 38 stores in 2010. For a given distributor/pharmacy/drug combination, all transactions subsequent to the first flagged transaction are also flagged. In the case of HBC, Dr. McCann does not explain why it is reasonable to flag all transactions involving GERx, which began shipping Schedule II opioids to Giant Eagle pharmacies in March 2016, 18 months after HBC ceased shipping HCP and codeine combination products to Giant Eagle pharmacies.

151. To illustrate the fact that Dr. McCann's "maximum monthly, trailing six-month threshold" approach merely identifies stores that were experiencing overall sales growth, I have prepared Exhibit M, which presents four examples of his application to the Giant Eagle data. Using his "maximum monthly, trailing six-month threshold" approach, Dr. McCann concludes that the earliest flagged transaction between HBC and Giant Eagle store #0218, located in Garfield Heights (Cuyahoga County), involving any product with the API hydrocodone was on August 29, 2010 (the first example presented in Exhibit M.) This is based on a determination that the monthly total dosage units for all transactions between HBC and store #0218 was 10,030, which is greater than the trailing six-month maximum of 9,330 dosage units observed in June 2010. He further determines that within the month of August 2010, the transaction on

[84] The 39th store, #4088 in Cuyahoga county, reported the first shipment of HCP on April 23, 2012.

August 29, 2010 caused the cumulative monthly total dosage units shipped by HBC to the store to exceed the threshold of 9,330. My Exhibit M also reports total growth in prescriptions filled by the pharmacy between Dr. McCann's threshold month (June 2010 for store #0218) and the month of the first transaction (August 2010 for store #0218), and the monthly share of controlled prescriptions in the threshold month and the month of the first transaction. For store #0218, total monthly prescriptions grew 34% between June and August 2010. Over the same time interval, controlled substance prescriptions, as a share of all prescriptions filled, remained stable at 11%-12%. The growth in dosage units of HCP products shipped that Dr. McCann claims should have been flagged for investigation can be simply explained as a consequence of overall growth in business at store #0218 over the three-month period. The example of store #0218 illustrates my conclusion that Dr. McCann's "maximum monthly, trailing six-month threshold" approach is incapable of distinguishing between periods when total sales are increasing and periods when sales of a particular product are increasing in a manner that could warrant further investigation.

E. Twice Trailing Twelve-Month Average Pharmacy Dosage Units

152. Dr. McCann describes his "twice trailing twelve-month average pharmacy dosage units" transaction analysis approach using the following language: "I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor." It is important to note that this approach does not create a store specific threshold. Consequently, in addition to all the systemic flaws in Dr. McCann's transaction analyses, which I discussed at the beginning of this section, there are three additional flaws specific to the trailing twelve-month average approach. The first flaw is that for any given month, the threshold is based on monthly average sales for all stores to which the distributor

shipped.[85] For this reason, this approach is inherently biased against stores with a larger volume of prescriptions dispensed to a larger patient base. The second flaw specific to the trailing twelve-month average approach is that, as Dr. McCann has implemented it, the Giant Eagle pharmacies that were not flagged during the period in which HBC was shipping Schedule III opioids (November 2009 - September 2014) are flagged using only one to seven months of transaction data in 2016. A third flaw is that, as implemented, this approach is logically inconsistent with Dr. McCann's assumption in the "maximum monthly, trailing six-month threshold" approach that monthly total transaction volume of 1,000 dosage units or less should not have been flagged for investigation. I discuss these approach-specific flaws in more detail below.

153. Under his twice trailing twelve-month average method, Dr. McCann flags HBC HCP transactions at six of Giant Eagle's largest pharmacies between November 2010 (the thirteenth month after HBC began shipping HCP to Giant Eagle pharmacies) and January 2011, and a seventh store in April 2013. Dr. McCann flags transactions involving all of the remaining 32 Giant Eagle pharmacies in Cuyahoga and Summit counties in 2016, long after HBC had ceased shipments of opioids to GE pharmacies. Using this approach for HCP transactions, he flags one store in April 2016 and the remaining 31 stores in September 2016 (17 pharmacies) and October 2016 (14 pharmacies). Notably, in April 2016, GERx had been shipping HCP to Giant Eagle pharmacies for only one month; GERx began shipping HCP in mid-March 2016. Thus, the threshold he uses to evaluate April 2016 shipments is based on only one month (March 2016) of prior transactions, not twelve months as stated in his report. The threshold he uses to evaluate and flag September 2016 shipments is based on only six months (March-September 2016) of

[85] My review Dr. McCann's of extensive reliance materials is ongoing and I may supplement my opinions as a result.

prior transactions, not twelve months as stated in his report. The threshold he uses to evaluate and flag October 2016 shipments is based on only seven months (March-October 2016) of prior transactions, not twelve months as stated in his report.

154. The "twice trailing twelve-month average pharmacy dosage units" and method is logically inconsistent with the "Maximum Monthly, Trailing Six-month Threshold" method because the 6-month metric assumes that for all distributor/pharmacy/drug combinations the threshold cannot be less than 1,000 dosage units. In contrast, the "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" approach does result in initially flagged transactions based on a threshold of less than 1,000 dosage units per month. For instance, the threshold for monthly HCP transactions in April 2016, under the twice trailing twelve-month average approach, was [redacted] dosage units. Dr. McCann calculates this threshold based solely on HCP transactions in March 2016. GERx shipped two orders of HCPs totaling [redacted] dosage units on April 12, 2016 to Giant Eagle Pharmacy #1263. These were the only transactions between GERx and pharmacy #1263 in April 2016. Based on the threshold of [redacted] dosage units, Dr. McCann flags both shipments (and every HCP transaction for pharmacy #1263 thereafter). There are additional examples of Dr. McCann flagging other Giant Eagle pharmacies based on thresholds of less than 1,000 dosage units per month.

155. Based on my review of Dr. McCann's "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" approach, I conclude that Dr. McCann did not accurately explain his methodology and that the approach he used is internally, logically inconsistent. Moreover, Dr. McCann does not explain why this is a reasonable approach and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient

care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management.

F. Three Times Trailing Twelve-Month Average Pharmacy Dosage Units

156. Dr. McCann's "three times trailing twelve-month average pharmacy dosage units" approach is similar to the "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" I discussed above, with the exception that he multiplies the 12-month average by three rather than by two. The three times 12-month approach therefore suffers from the same fatal flaws, both systemic and specific to the trailing twelve-month average approach, that afflict the twice 12-month approach. It is biased against larger store volumes when calculated using 12-months of transactions.[86] The approach also results in 31 Giant Eagle pharmacies being flagged for HCP transactions in September and October 2016, before 12 months of GERx shipments have occurred.

157. Based on my review of Dr. McCann's "three times trailing twelve-month average pharmacy dosage units" approach, I conclude that Dr. McCann did not accurately explain his methodology and that the approach he used is internally, logically inconsistent. Moreover, Dr. McCann does not explain why this is a reasonable approach and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management.

G. Maximum 8,000 Dosage Units Monthly

158. Dr. McCann describes his "Maximum 8,000 Dosage Units Monthly" approach using the following language: "I identify transactions that cause the number of dosage units

[86] My review Dr. McCann's of extensive reliance materials is ongoing and I may supplement my opinions as a result.

shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units." In addition to the systemic flaws that afflict all of Dr. McCann's transaction analyses, there are several fatal flaws specific to the "Maximum 8,000 Dosage Units Monthly" approach. First, although Dr. McCann does not discuss the basis for the 8,000 dosage unit threshold in his report, I understand that this is a metric that McKesson may have developed and/or used at some point in time.[87] Dr. McCann provides no explanation for why it is reasonable to apply a metric developed by a third party to HBC transactions. Second, a hard limit such as 8,000 monthly dosage units is biased against larger stores. Third, according to Dr. McCann, McKesson used this metric for oxycodone, with no indication as to whether it applied to all formulations or just some. Additionally, it is not clear whether McKesson used this metric to evaluate shipments of other opioids, such as HCP or codeine. Dr. McCann provides no justification for why an 8,000-dosage-unit threshold is relevant for all formulations of oxycodone and no basis for his use of this metric as a threshold for shipments of drugs other than oxycodone.

H. Maximum Daily Dosage Units

159. Dr. McCann describes his "maximum daily dosage units" approach using the following language: "I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation." Although, as of today, I have not been able to evaluate the basis for the thresholds Dr. McCann uses in his "Maximum Daily Dosage Units" approach,[88] I note that the results of this approach are absurd. For example, for HCPs, the very first transaction is flagged for all 39 Giant Eagle pharmacies in the two counties (i.e., the first

[87] My review Dr. McCann's of extensive reliance materials is ongoing and I may supplement my opinions as a result.

[88] I have been unable to locate the source documents that Dr. McCann claims to have relied on as the basis for his maximum daily dosage unit thresholds.

day HBC ships HCPs). I will supplement my opinions regarding this approach after I have been able to review and evaluate the source documents that Dr. McCann claims to have relied on for this approach.

I. Chain Distributor Transactions Analyses

160. In section IX.F of his report, Dr. McCann describes an additional set of transaction analyses he conducted, which he describes as "additional identification" in the section title and a "chain distributor" transaction analyses in the text of his report and his reliance materials. Dr. McCann describes his "chain distributor" transaction analyses using the following language: "I have been asked by Counsel to assume that Chain Distributors may have had knowledge of – or information available to inform them of – opioid shipments from all Distributors to the Chain Distributor's affiliated pharmacies. I have re-run the five identification routines described above assuming that the Chain Distributors could have flagged transactions based on this expanded information set…"

161. In addition to the systemic and approach-specific flaws I describe above, Dr. McCann's "chain distributor" transaction analyses suffer from two additional glaring errors with respect to HBC. First, Dr. McCann's "chain distributor" transaction analyses assume that HBC can be liable for the actions of other distributors in the market. Second, Dr. McCann concludes that HBC is responsible for monitoring distributor transactions before it was in the business of distributing Schedule III-V controlled drugs to Giant Eagle pharmacies (i.e., before November 2009).

162. These analyses are conducted over the period 2006-2014, based on all distributor transactions with Giant Eagle pharmacies. For all opioids at issue in this case, Dr. McCann flags a large number of transactions before HBC started shipping opioids to Giant Eagle pharmacies. For example, Dr. McCann performed the analysis on the pharmacy/drug level, and he did start

flagging transactions before 2009. For example, for Giant Eagle pharmacy #0209 for the Codeine (9050) products, the first failed flagged transaction using all distributor transaction data and the "Twice Trailing Twelve-Month Average Pharmacy Dosage Units" approach is February 26, 2007 (a shipment from McKesson). This store did not receive shipments of codeine combination products from HBC before October 12, 2009. Another example is HCP shipments to Giant Eagle pharmacy #1216. The first failed flagged transaction using all distributor transaction data and the "Maximum Monthly, Trailing Six-month Threshold" approach is August 28, 2006 (a shipment from McKesson). The first transaction Dr. McCann flags under the 6-month threshold is from McKesson on August 28, 2006. This store did not receive shipments of hydrocodone combination products from HBC before October 12, 2009. For HCPs, Dr. McCann flagged 41,568 transactions between January 3, 2006 and November 11, 2009. For all of these transactions involved, Giant Eagle was not the distributor. Moreover, during this period HBC was not a distributor; the company did not ship a single dosage unit of any opioid to any pharmacies. See Exhibit N.

163. Dr. McCann does not explain why the "Chain Distributor" approach analyses is reasonable and whether the results of this approach are reasonable. I see no basis of support for this approach in the principles of patient care, distribution of pharmaceuticals, distribution of controlled substances or pharmacy supply and management.

VII. ORDERS IDENTIFIED BY PLAINTIFFS AS SUSPICIOUS WERE BASED ON VALID PRESCRIPTIONS DISPENSED UNDER THE PROPER AUTHORITY

164. Plaintiffs identified 30 HBC orders that they claim are suspicious.[89] I understand from counsel for HBC that Giant Eagle determined that none of these orders were suspicious based on a thorough investigation of the associated prescriptions. My review of these orders, including the size and frequency of other orders during the relevant periods, did not identify a suspicious pattern.

165. The Giant Eagle pharmacy located in Barberton, Ohio (#4031) is the buyer for all 10 orders identified by plaintiffs in the supplemental interrogatory dated January 11, 2019 and in 2 of the 20 orders identified by plaintiffs in the amended supplemental interrogatory dated January 25, 2019. The Barberton store is the largest among all Giant Eagle pharmacies in Summit and Cuyahoga counties, with the greatest number of total prescriptions and controlled substance prescriptions dispensed during the period from November 2009 through May 2018. The Barberton pharmacy is across the street from the Akron Children's Hospital and within one mile of the Summa Health System Barberton Campus.

166. I have reviewed the transaction history for controlled substance orders from HBC to this store and I find that the ordering practices at the Barberton store reflect pharmacy best practices. Title 21 of the Code of Federal Regulations Section 1301.74(b) provides that distributors of controlled substances identify "…[suspicious] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[90] The pattern of orders shipped from HBC to Barberton reflects some variability during the first few months of

[89] Plaintiffs Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs, January 11, 2019; Plaintiffs Responses to Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs, January 25, 2019.

[90] US Drug Enforcement Administration Title 21 Code of Federal Regulations. Diversion Control Division, available at: https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/130174 htm (last accessed May 10, 2019).

HBC operation (November 2009 through March 2010), a startup period. After this initial startup period, I find that the frequency of orders placed from the Barberton store to HBC is regular, consistently following a pattern of ordering controlled substances every other day ([redacted] days between orders) for the period that HBC shipped HCPs to Barberton. See Exhibit O. The size of orders shipped to the Barberton store also is consistent, with differences in order size reflecting normal variation in demand and some variability in the size of orders because the Barberton store receives shipments of controlled substances from other distributors in addition to HBC. See Exhibit P.

167. I find that the Barberton store maintained a fairly constant share of controlled substance prescriptions relative to total prescriptions dispensed between 2009 and 2018, generally following the same trend as for total prescription dispensed, which grew from 2008 - 2011 leveled off in 2012 and then declined from 2013 to 2018 (both controlled substance and non-controlled prescriptions declined). See Exhibit Q. The share of controlled substance prescriptions to total prescriptions dispensed at the Barberton store was 13.9% over the period from November 2009 to May 2018, with a maximum in any month of 18.5%, which is above the average for all Giant Eagle pharmacies in Summit and Cuyahoga counties but is below the expected ratio for legitimate retail pharmacies.[91]

VIII. CONCLUSION

168. In summary:

- Giant Eagle owns and operates an exemplary pharmacy organization and distribution network that is committed to the safety, health and wellness of their patients and the communities they serve.

[91] Deposition of Kyle J. Wright, February 28, 2019, at 260:1-22.

- Giant Eagle enables policies, procedures and industry practices to prevent theft and diversion of all prescription products. Intense and regular reviews of prescriptions, replenishment orders and inventory management systems prevent illegitimate prescriptions to be filled in the pharmacy and for suspicious orders to be filled by the distribution center. Because of their robust and cohesive controls and processes that have evolved over time, it is not surprising that Giant Eagle does not have many suspicious orders to report to the DEA.
- Despite implementing a threshold system to monitor for suspicious orders, there was no change in the number of suspicious orders, validating that existing policies and procedures were sufficient to prevent theft and diversion.
- Giant Eagle is, and always has been, compliant with the Controlled Substances Act. The DEA believes that Giant Eagle provides effective controls and procedures by inspecting their stores and distribution center regularly and issuing licenses to operate. The State of Ohio Board of Pharmacy believes that Giant Eagle provides effective controls and procedures by inspecting their stores and distribution center regularly and issuing licenses to operate. And, the State Boards of Pharmacy for Pennsylvania, West Virginia, Maryland and Indiana all believe that Giant Eagle provides effective controls and procedures by inspecting their stores and distribution center regularly and issuing licenses to operate.

Sandra K.B. Kinsey, M.B.A., R.Ph.

Date: June 3, 2019

EXHIBIT A: CURRICULUM VITAE FOR SANDRA KINSEY

Curriculum Vitae
of
Sandra KB Kinsey, R.Ph, MBA

17 Darian Drive
Bentonville, AR 72712
Phone: (479)381-6522
Email: skbkinsey@gmail.com

Summary

Sandy Kinsey is an executive retail consultant who provides strategic direction and visionary leadership for high-profile organizations and assists industry leaders in developing comprehensive strategies for growth within the retail pharmacy market. She is recognized as a leader in transforming health care through the development of unique and innovative, customer-focused initiatives centered on delivering quality products and services. She is an inspirational leader and mentor, building top-performing teams for operational excellence in various, cross-functional organizations. Ms. Kinsey possesses a unique blend of competencies including business strategy, clinical expertise, merchandising, operations, and corporate integration to design and deliver exceptional results.

Ms. Kinsey is a Registered Pharmacist and corporate executive with several years of experience in business strategy design and implementation, pharmacy operations, merchandising, financial management, marketing, wholesale distribution, product procurement and supply chain, and new item development. Throughout her 17-year career at Walmart, she acquired a breadth of retail pharmacy experience by serving in a variety of roles within Pharmacy Operations, Merchandising, Technology, and Compliance. Ms. Kinsey also works with independent pharmacies on improving operational efficiencies, marketing, and customer service.

In addition to her continued work to influence retail pharmacy, Ms. Kinsey also serves as an expert witness and subject matter expert in several areas of litigation. Specializing in pharmacy practice, she provides a unique and reliable perspective to matters related, but not limited to, the prescription dispensing process, insurance claims, product purchasing and distribution, drug substitution, technology integration and corporate and local standards of practice.

Ms. Kinsey is a polished communicator and key opinion leader who is well connected with people of influence in retail, health care, wholesale drug distribution, and other leading corporations. She received several Walmart awards in leadership, sits on the Dean's Advisory Council for the UMKC School of Pharmacy, is the Vice President of the Board of Directors for Arkansas Youth Bridge, and is an active participant in the Network for Executive Women. Ms. Kinsey earned an MBA with honors and a BS in Pharmacy from the University of Missouri – Kansas City.

Education/Licensing

- Masters Business Administration: Kaplan University
- Bachelor of Science, Pharmacy: University of Missouri, Kansas City
- Pharmacy Doctor: Licensed in Arkansas, 1996 to present
- Registered Pharmacist: Licensed in Kansas 1992 to present

Professional Experience

KINSEY PARTNERS LLC 2014-Present
[Retail Healthcare Consulting for public and private companies.]
President
Assist industry leaders in developing comprehensive strategies for growth within the retail and healthcare sectors. Specialties include business development and collaboration, corporate and field operations, pharmacy/OTC merchandising, product procurement and supply chain, mentoring and executive coaching, communications planning and consumer engagement. Contracted companies include Walgreens, Teva, Sandoz, Amneal, Lupin, Apotex, Aurobindo, Omron, Lifescan, Abbott, Prestige, AmerisourceBergen, Anda, Legacy Packaging, MeadWestVaco, and others.

Expert witness with testifying experience in cases that relate to retail pharmacy and prescription filling. Experience includes patent and trademark infringement, false advertising, unfair competition, and prescription errors.

HIGHLANDS PHARMACY, Rogers, AR 2019 - Present
[Highlands Oncology Group - nationally recognized cancer treatment center.]
Pharmacist
Provide a full suite of pharmacy services in a unique and innovative clinic and research facility dedicated to cancer patients. Specialize in care team coordination, medication management, side effect monitoring, education, financial assistance, etc.

WALGREENS, Chicago, IL 2018 – 2019
[Second largest pharmacy chain in the US, operating in all 50 states.]
Business Assurance Consultant
Assist leadership in the design, implementation, and deployment of a new healthcare technology platform that will support approximately 10,000 pharmacies and provide sustainable growth for the near future. Assess current roadmap and planned design, evaluating against expected business and operational outcomes to identify gaps and recommend risk mitigation strategies.

ARKANSAS SPECIAL OLYMPICS, Little Rock, AR 2016 – Present
[Provide sports training and competition for all children and adults with intellectual disabilities.]
Volleyball Tournament Director and Sponsor
Annually design and execute the largest volleyball tournament in Northwest Arkansas for special needs children and adults. Recruit players, volunteers and sponsors to support the mission of Special Olympics, through team play and education.

YOUTH BRIDGE, INC., Fayetteville, AR 2015 – Present
[Providing safe, supportive and empowering services to teens and families during hard times.]
Chairman, Board of Directors
Youth Bridge is the only organization in Northwest Arkansas that offers clinical and behavioral-based programs exclusively for youth and their families in both residential and outpatient environments. The organization offers multi-disciplinary professional teams to produce optimum results and fosters a collaborative approach with other agencies.

WALMART INC., Bentonville, AR 2007 – 2014
[World's largest public corporation with 2+ million employees and annual revenues over $480 billion.]
Vice President, Pharmacy Merchandising, Health & Wellness (2009-2014)
An officer of the company, served as Chief Merchant for Pharmacy and member of the Health & Wellness Executive Leadership Team, positioning Walmart as a health and wellness destination for quality healthcare

products and services. Developed divisional strategies and executed a business model in an integrated network that successfully increased traffic into the stores from multiple platforms, exceeding the national growth averages, and delivering more than $15 billion in revenues. Continued responsibility for sales and gross profit of the entire division. Leader in cross-functional teams and highly matrixed organization with concentrated connection to third party payers, operations, finance, legal, and clinical compliance, keeping the customer/patient as the core focus.

- Responsible for strategy and execution of business expansion for retail operations, central fill and mail order, specialty pharmacy, and six Rx distribution centers.
- Successfully forecasted and managed P&L through variable demand models related to large brand to generic conversions and operational excellence, exceeding sales and profit targets.
- Designed and managed all aspects of the inter-dependent relationship between Walmart, McKesson, and all Rx suppliers, including procurement, supply chain, central fill, specialty pharmacy, systems and technology.
- Positioned Walmart Pharmacy as a preferred health and wellness destination for the Medicare, Medicaid, and commercial insurance customer through formulary design and incentive drivers for growth in Rx and OTC.
- Collaborated extensively with Operations on innovative health care solutions that generated operational performance and achievement of a common goal to exceed customer expectations and lower the overall cost of healthcare.

Senior Director, Rx Procurement and Supply Chain (2007-2009)

Led the team in world-class drug development, procurement, pricing, and inventory management for over 4100 stores and clubs. Primary responsibility for sales, profit, and inventory of the Rx Division.

- Developed and maintained the $4 Pharmacy Program, saving customers over $5 billion since September 2006. The program continues to disrupt the industry as a core component in driving low cost healthcare and preferred network contracts.
- Negotiated multi-year contracts for product procurement and supply from wholesalers and direct suppliers to ensure optimum portfolio management and highest levels of customer service at store level.

SAATCHI & SAATCHI X, Fayetteville, AR 2006 – 2007

[Global leader and pioneer of Shopper Marketing and member of the Publicis Groupe.]

Retail Health Strategist/Account Director

Global subsidiary of Saatchi & Saatchi that specializes in developing retail shopper initiatives and solutions for top CPG and retail Fortune 500 companies. Led global health and wellness initiatives for multiple clients and directly managed the account for Novartis Consumer Health and Novartis Pharmaceuticals. Key responsibilities included strategic thought leadership in the development and management of marketing programs, promotions, research/insights, creative and execution.

REDICLINIC, Houston, TX 2004 – 2006

[Healthcare company that manages retail medical clinics focused on high-quality, affordable services.]

SVP/General Manager

Led the team towards an innovative, new strategy to broaden initial product offering (employer and retail screenings) to a nationally branded, retail-based, limited service offering medical clinic in permanent locations. Key responsibilities included concept development and substantiation, private equity funding, regulatory lobbying, operations, contract insurance negotiation, technology infrastructure, legal, marketing, organizational and people development.

ELI LILLY & COMPANY, Indianapolis, IN 2004

[Fortune 500 organization and 10th largest global pharmaceutical company with $20B in sales.]

Senior Sales Representative

Specializing in primary care and neuroscience. Consistently exceeded company and local market quotas while managing a territory with more than 500 health care practitioners.

WALMART INC., Bentonville, AR 1992 – 2004

[World's largest public corporation with 2+ million employees and annual revenues over $431 billion.]

Director, Pharmacy Marketing/Buyer (2002-2004)

Led the Walmart Pharmacy Marketing team through multiple in-store initiatives and constant integration with senior marketing executives of larger format to complete store-within-a-store concept. Also responsible for purchasing and inventory of key pharmaceutical categories. Key responsibilities included marketing program development and execution, shopper research, pharmacy industry relations, purchasing, inventory, and strategic design.

Director, System Design and Implementation (1999-2002)

Led team in development of proprietary prescription filling software (*Connexus*™) using state-of-the-art technology and building a foundation for future growth. Key responsibilities included industry intelligence, functional design, distribution strategy, accuracy and productivity of employees, sales results, customer satisfaction, operations, training and marketing.

Director, Operations and Quality Assurance (1996-1999)

Established and maintained standards of excellence for customer satisfaction, company-wide operations, communications, and employee development.

District Pharmacy Manager and Pharmacist (1992-1996)

Kansas City Metro Area

Full P&L responsibility and accountability for $5MM pharmacy/$75MM district including revenue generation, expense management, people development, and customer satisfaction.

EXHIBIT B: LITIGATION SUPPORT FOR SANDRA KB KINSEY

SANDRA KB KINSEY, RPH, MBA
History of Litigation Support/Expert Witness Experience

National Prescription Opioid Litigation **2019**
MDL 2804 Case No. 17-MD-2804
Representative Law Firm: Marcus & Shapira on behalf of Giant Eagle/HBC Service Company
Nature of Cases: Negligence, fraud, theft and diversion, failure to maintain effective controls, etc.

The County of Summit Ohio, et al., v. Purdue Pharma L.P., et al.
Case No. 18-op-45090, Northern District of Ohio

J&J Talcum Powder Litigation **2018**
Representative Law Firm: Barnes & Thornburg LLP on behalf of Retailers
Nature of Cases: Negligence, product liability, personal injury
Plaintiff alleges progressive lung disease, cancer and other serious diseases are caused by inhalation of asbestos fibers from exposure to Defendants' products.

Ardys Lane, etc. v. Albertsons Companies, Inc., etc.
Case No. RG18985870, Almeda County Superior Court, Oakland, California

Sharon Pipes & Andrew Slupski v. American Honda Motor Co, Inc., et al.
Case No. CJ2017-3487, District Court of Oklahoma County, State of Oklahoma

Donald Strain, etc. v. East Baton Rouge Parish School Board, et al.
Case No. 646985, 19th Judicial District Court, State of Louisiana

Blinkinsop v. Albertsons Companies, Inc., et al.
Case No. JCCP 4764/BC677764, Superior Court of California, County of Los Angeles

Carla Allen v. Brenntag North America Inc., etc., et al.
Case No. DR180132, Humboldt County, Superior Court of California

Heartland Medical LLC v. Express Scripts Inc. **2018**
Case No. 17CV02873, District Court of Missouri, Eastern Division
Representative Law Firm: Baker, Donelson, Bearman, Caldwell & Berkowitz PC on behalf of Heartland Medical
Nature of Case: Breach of contract, unjust enrichment, tortious interference
Plaintiff seeks to recover damages from the Defendant for wrongful withholding of over $1M for sales of diabetic testing supplies.

Concordia Pharmaceuticals Inc. v. Lazarus Pharmaceuticals Inc. **2018**
Case No. 18CV1658, District Court of South Carolina, Greenville Division
Representative Law Firm: Roe Cassidy Coates and Price PA on behalf of Lazarus Pharmaceuticals
Nature of Case: False advertising, unlawful sales and marketing
Plaintiff alleges that Defendant's sales, marketing and advertising of PBA Elixir as an approved generic for Donnatal Elixir® is unlawful and causes confusion and misleading behaviors with prescribers and pharmacists.

Valeant Pharmaceuticals LLC v. ECI Pharmaceuticals and Virtus Pharmaceuticals **2018**

Case No. 18CV00355, North District of California
Investigation No. 337TA1109, International Trade Commission
Representative Law Firm: Benjamin England and Associates, Husch Blackwell, and Amin Talati Upadhye on behalf of ECI Pharmaceuticals and Virtus Pharmaceuticals

Nature of Case: False Advertising; unlawful sales and marketing
Plaintiff alleges that Defendant's marketing and advertising of CDP tablets as an approved generic for Librax® was unlawful and caused confusion and misleading behaviors with prescribers and pharmacists.

James Jah v. Glenmark Generics, Inc., AmerisourceBergen Drug Corp. and others 2018
Case No. 14CV02420, Commonwealth of Massachusetts
Representative Law Firm: Greenberg Traurig LLP on behalf of Glenmark Generics and ABDC
Nature of Case: Negligence, breach of warranty
Plaintiff developed a severe allergic reaction to sulfamethoxazole/trimethoprim manufactured by the defendant and is seeking damages allegedly due to negligence and failure to warn by the manufacturer and wholesale distributor.

Takeda Pharmaceuticals Inc. v. West-Ward and Hikma Pharmaceuticals Inc. 2017
Case No. 14CV01268, District Court of Delaware
Representative Law Firm: Goodwin Proctor LLP on behalf of West-Ward/Hikma Pharmaceuticals
Nature of Case: Patent infringement, false advertising
Patent infringement, false advertising and sale of defendant's brand drug Mitigare™ and authorized generic version of Colchicine 0.6mg capsules in relation of plaintiff's brand drug Colcrys®.

Concordia Pharmaceuticals Inc. v. Winder Laboratories LLC and Steven Pressman 2017
Case No. 16CV00004, District Court of Georgia, Gainesville Division – *Claim and Counterclaim*
Representative Law Firm: Venable LLP on behalf of Winder Laboratories
Nature of Case: False advertising, unlawful sale and distribution
Claim: Concordia alleges that Winder's sales, marketing and advertising of Phenohytro as an approved generic for Donnatal® tablets is unlawful and causes confusion and misleading behaviors with prescribers and pharmacists.
Counterclaim: Winder alleges that Concordia's misrepresentation of the facts, false advertising, and legal activities delayed drug launch and irreparably damaged the company's ability to succeed as forecasted and is seeking recovery of damages.

GlaxoSmithKline Inc. v. Teva Pharmaceuticals Inc. 2016
Case No. 14CV00878, District Court of Delaware
Representative Law Firm: Goodwin Proctor LLP on behalf of Teva Pharmaceuticals
Nature of Case: Patent infringement, false advertising, inducement
Patent infringement based on defendant's manufacture and sale of its generic version of GSK's Coreg® for all indications, despite label carve out for congestive heart failure.

GlaxoSmithKline Inc. v. Glenmark Pharmaceuticals Inc. 2016
Case No. 14CV00877, District Court of Delaware
Representative Law Firm: Winston & Strawn LLP on behalf of Glenmark Pharmaceuticals
Nature of Case: Patent infringement, false advertising, inducement
Patent infringement based on defendant's manufacture and sale of its generic version of GSK's Coreg® for all indications, despite label carve out for congestive heart failure.

Amneal Pharmaceuticals LLC v. Reckitt Benckiser Pharmaceuticals Inc. & Idivior Inc. 2016
Case No. 15CV08864, District Court of New Jersey
Representative Law Firm: Venable LLP on behalf of Amneal Pharmaceuticals
Nature of Case: Anticompetitive conduct, false advertising
Plaintiff alleged illegal acts of deception to delay development of and generic launch of competitive products for Suboxone® (buprenorphine/naloxone).

Concordia Pharmaceuticals Inc. v. Winder Laboratories LLC and Steven Pressman 2016
Case No. 16CV00004, District Court of Georgia, Gainesville Division

Representative Law Firm: Venable LLP on behalf of Winder Laboratories
Nature of Case: Trademark infringement, false advertising
Plaintiff alleged that Defendant's marketing and advertising of B-Donna™ tablets as an approved generic for Donnatal® caused irreparable injury and was seeking preliminary injunction on distribution and damages.

URL Pharma Inc., et al. v. Reckitt Benckiser, Inc 2016
Case No. 15CV00505, District Court, Eastern District of Pennsylvania
Representative Law Firm: Arent Fox LLP on behalf of Reckitt Benckiser
Nature of Case: Anti-trust violations, breach of contract
Plaintiff alleged Defendant maintained monopoly power in the market for Mucinex® through exclusionary, anticompetitive conduct, including withholding supply, which violated the previous settlement agreement.

EXHIBIT C: LIST OF MATERIALS REVIEWED OR CONSIDERED

Pleadings and Materials Related to Pleadings

1. Summit County Corrected Second Amended Complaint and Jury Demand, filed May 29, 2018.
2. Distributor Defendants' Memorandum in Support of Motion to Dismiss, filed May 25, 2018.
3. Retail Pharmacies' Memorandum in Support of Motion to Dismiss, As amended, May 25, 2018.
4. Plaintiffs' Omnibus Memorandum in Opposition to all Defendants' Motion to Dismiss, filed June 22, 2018.
5. Reply in Support of Motion to Dismiss Complaint by Pharmacy Defendants, filed July 13, 2018.
6. Distributors' Reply in Support of Motion to Dismiss, filed July 13, 2018.
7. Magistrate's Report and Recommendation on Motions to Dismiss, filed October 5, 2018.
8. Order Regarding Rejections to Report and Recommendation, filed October 10, 2018.
9. Opinion and Order, filed December 19. 2018.
10. Manufacturer Defendants' Fourth Set of Interrogatories to Plaintiffs County of Summit and City of Akron, filed January 19, 2019.
11. Defendant HBC Service Company's Answer and Affirmative Defenses to Corrected Second Amended Complaint, filed, January 15, 2019.
12. Plaintiff's Written Responses to Defendants' Rule 30(b)(6) Topic No. 14, filed February 5, 2019.
13. Special Master Cohen Discovery Ruling No. 1, filed June 11, 2018.
14. Special Master Cohen Discovery Ruling No. 2, filed June 30, 2018.
15. Special Master Cohen Discovery Ruling No. 3, filed July 17, 2018.
16. Special Master Cohen Discovery Ruling No. 4, filed September 21, 2018.
17. Special Master Cohen Discovery Ruling No. 5, filed October 6, 2018.
18. Special Master Cohen Discovery Ruling No. 6, filed October 15, 2018.
19. Special Master Cohen Discovery Ruling No. 7, filed October 21, 2018.
20. Special Master Cohen Discovery Ruling No. 8, filed October 23, 2018.
21. Special Master Cohen Discovery Ruling No. 9, filed October 29, 2018.
22. Special Master Cohen Discovery Ruling No. 10, filed November 28, 2018.
23. Special Master Cohen Discovery Ruling No. 12, filed December 9, 2018.
24. Special Master Cohen Discovery Ruling No. 13, filed December 22, 2018.
25. Special Master Cohen Discovery Ruling No. 14, Part 1, Regarding Privilege and Claw-Back, filed January 31, 2019.
26. Special Master Cohen Discovery Ruling No. 14, Part 2, Regarding Mallinkrodt Privilege Log, filed February 9, 2019.
27. Special Master Cohen Discovery Ruling No. 14, Part 3, Regarding Common Interest Privilege (Agenda Item No. 154), filed January 31, 2019.
28. Special Master Cohen Discovery Ruling No. 15, Regarding IQVIA Discovery, filed February 15, 2019.

29. Special Master Cohen Amendment to Discovery Ruling No. 14, Part 1, Regarding Privilege and Claw-Back, filed February 20, 2019.
30. Special Master Cohen Discovery Ruling No. 16, Part 1, Regarding DEA Depositions, filed February 22, 2019.
31. Special Master Cohen Discovery Ruling No. 14, Part 4, Regarding Walgreens Privilege Log, filed February 22, 2019.
32. Special Master Cohen Amendment to Discovery Ruling No. 14, Part 4, Regarding Walgreens Privilege Log, filed February 26, 2019.
33. Special Master Cohen Discovery Ruling No. 17, Regarding SACWIS Data, filed March 10, 2019.
34. Special Master Cohen Discovery Ruling, No. 18, Regarding Prescriptions and Dispensing Data, filed March 26, 2019.
35. Responses and Objections to Manufacturer Defendants' Interrogatory No. 33, filed March 28, 2019.
36. Special Master Cohen Discovery Ruling No. 14, Part 5, Regarding Privilege Claim on Cardinal's Dendrite Audit, filed March 31, 2019.
37. Special Master Cohen Discovery Ruling No. 19, Regarding Dr. Portenoy, filed April 5, 2019.
38. HBC Service Company's Second Supplemental Answers to Plaintiffs' First Set of Interrogatories to HBC Service Company, dated March 29, 2019.
39. Plaintiffs' Responses to Supplemental Interrogatory Issued in Discovery Ruling 12 to Plaintiffs, dated January 11, 2019.
40. Special Master Cohen Discovery Ruling, No. 14, Part 6, Regarding Cardinal Health Privilege Claims, filed April 29, 2019.
41. Special Master Cohen Discovery Ruling, No. 14, Part 7, Regarding CVS's Dendrite and DCAG Audit Reports, filed May 3, 2019.

Expert Reports, Including Exhibits Therein

1. Expert Report of Craig J. McCann, dated March 25, 2019
2. Supplemental Expert Report of Craig J. McCann, dated April 3, 2019
3. Expert Report of Dr. Seth B. Whitelaw, dated April 15, 2019
4. Expert Report of Lacey R. Keller
5. Expert Report of James E. Rafalski, dated April 15, 2019
6. Expert Report of Dr. Stephen W. Schondelmeyer, dated April 15, 2019

Depositions, Including Exhibits Therein

1. Deposition of Jim Tsipakis (Rule 30 (b)(6), December 13, 2018
2. Deposition of Joseph Millward, December 20, 2018
3. Deposition of Anthony Mollica, January 4, 2019
4. Deposition of Greg Carlson, January 8, 2019
5. Deposition of George Chunderlik, January 16, 2019

6. Deposition of Michael Bianco, January 18, 2019
7. Deposition of Fred Bencivengo, January 22, 2019
8. Deposition of Walter Durr, January 22, 2019
9. Deposition of Robert McClune, January 25, 2019
10. Deposition of Randy Heiser, February 19, 2019
11. Deposition of Philip Raub, February 19, 2019
12. Deposition of Matthew Rogos, February 22, 2019
13. Deposition of Kyle J. Wright, February 28, 2019
14. Deposition of Stacy Harper-Avilla, April 11, 2019.
15. Deposition of Thomas Provoznik, dated April 17-18, 2019

Websites, Articles, and Other Online Materials

1. Albert, E. Debunking the Myths of Controlled Substance Quotas. *Pharmacy Times*. June 1, 2018 *available at* https://www.pharmacytimes.com/publications/career/2018/careersspring2018/debunking-the-myths-of-controlled-substance-quotas (last accessed May 3, 2019).
2. Bondell, R., Azadfard, M., and Wisniewski, A. Pharmacologic Therapy for Acute Pain. *American Family Physician*. 2013 Jun 1:87(11):766-772 *available at* https://www.aafp.org/afp/2013/0601/p766.html (last accessed May 3, 2019).
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Statutory and Regulatory Materials

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2. 21 C.F.R. §§ 1301, 1301.11, 1301.71-1301.76, 1303, 1304.11, 1306.04.
3. 21 U.S.C. § 812
4. 21 USC § 826
5. 21 CFR §1303
6. 21 C.F.R. § 205
7. 47 O.R.C § 4729.51-53
8. Ohio Administrative Code 4729-9-14
9. 21 CFR §1301.71

Bates Numbered Documents

1. HBC_MDL0018194
2. HBC_MDL0018196
3. HBC_MDL0018197
4. HBC_MDL0018199
5. HBC_MDL0018200
6. HBC_MDL0018202
7. HBC_MDL0018203
8. HBC_MDL0018204
9. HBC_MDL0018206
10. HBC_MDL00189211
11. HBC_MDL00189212
12. HBC_MDL00189213
13. MDLSBCDMDL00269687
14. MDLSBCDL00269685
15. MDLSBCDL00269683
16. HBC_MDL00132616

Company Data

1. Weekly Rx Volume by store (A1366710).xlsx

EXHIBIT D: HBC/GERX SHARE OF PRESCRIPTION OPIOIDS DISTRIBUTED IN SUMMIT AND CUYAHOGA COUNTIES

	By MME			By Dosage Units			Source
	HBC/GERx	All Distributors	HBC/GERx Share	HBC/GERx	All Distributors	HBC/GERx Share	
	January 1, 1996 - June 29, 2018						
Dr. McCann's Dataset [1]	[redacted]						[A]
	January 1, 2006 - December 31, 2014						
Transactions Reported in Table 13 of Dr. McCann's Report [2]	[redacted]			N/A	N/A	N/A	[B]
Transactions Reported in Table 14 of Dr. McCann's Report [2]				N/A	N/A	N/A	[B]

Notes:

[1] Dr. McCann's dataset comprises transactions from ABDC, Anda, Cardinal, CVS, DDM, HBC, HD Smith, HSI, McKesson, Miami Luken, PSI, Rite-Aid, Wal-Mart, and Walgreens in Cuyahoga and Summit county until December 31, 2014 (the last date of ARCOS data). After December 31, 2014, Dr. McCann uses defendant data for ABDC, Anda, Cardinal, HBC, McKesson, PSI, and Wal-Mart. Duplicate transactions for Giant Eagle pharmacies that are located in Cleveland, Ohio from March 2016 and May 2018 are excluded from this analysis. Giant Eagle pharmacy #0515 is also excluded, because it is located outside of Cuyahoga, OH.

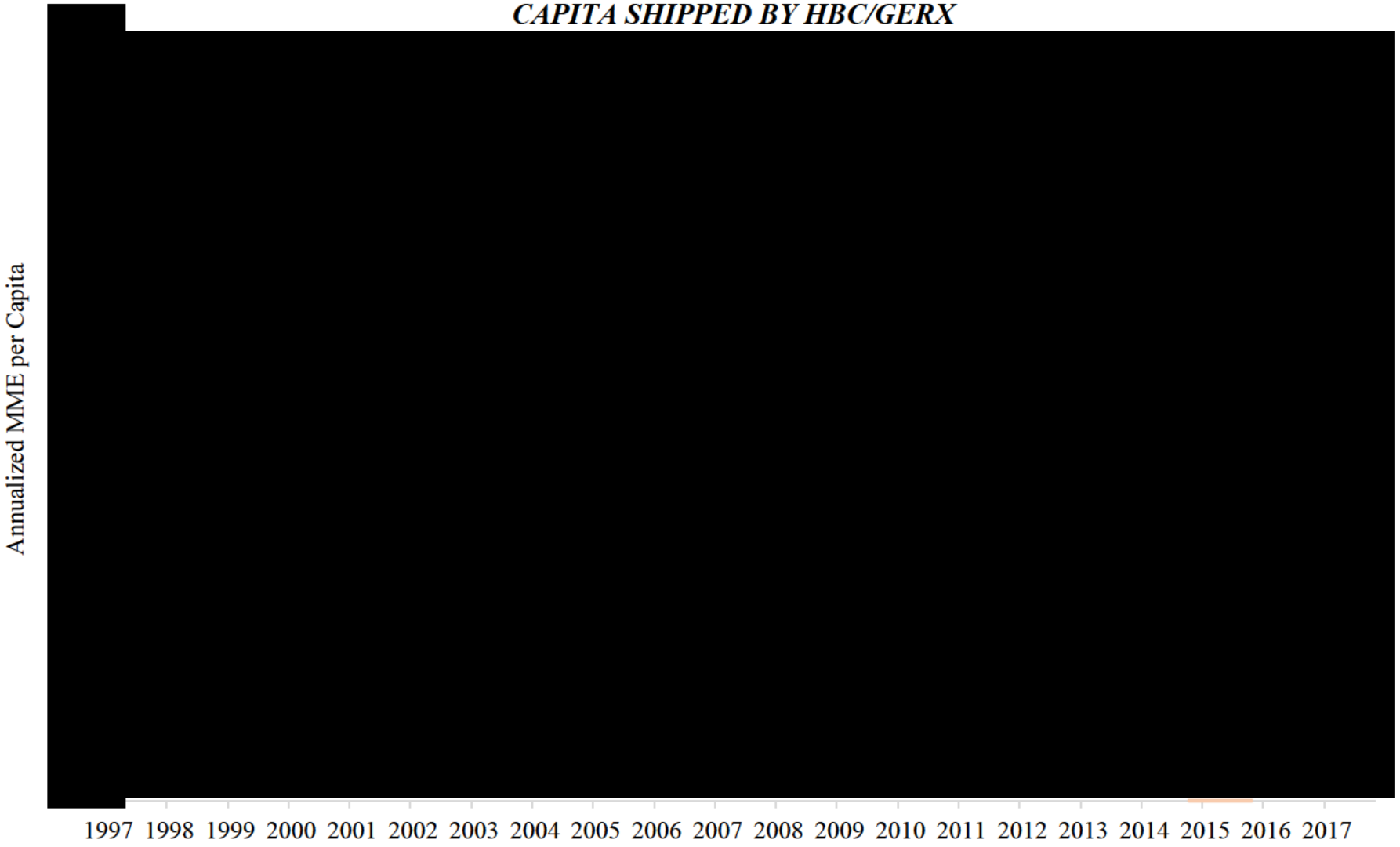
[2] McCann's Table 13 and McCann's Table 14 include buprenorphine and methadone transactions, although the transactions data used in the "Dr. McCann's Dataset" calculations do not. I examined Dr. McCann's reliance materials but was unable to modify his Table 13 and Table 14 analysis in a way that would produce results based on dosage units corresponding to the results based on MME.

Sources:

[A] Files "ABDC.xlsx", "Anda.xlsx", "Cardinal.xlsx", "CVS.xlsx", "DDM.xlsx", "HBC.xlsx", "HD Smith.xlsx", "HSI.xlsx", "McKesson.xlsx", "Miami Luken.xlsx", "PSI.xlsx", "Rite-Aid.xlsx", "Walgreens.xlsx", and "Wal-Mart.xlsx" available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MDL Code Submission 4.23.2019\MATLAB Code for Flagged Transactions\Code Production\Input Transactions\"

[B] Table 13 and Table 14 in Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019.

EXHIBIT E: TOTAL PER CAPITA MME SHIPPED IN CUYAHOGA COUNTY VS. PER CAPITA SHIPPED BY HBC/GERX



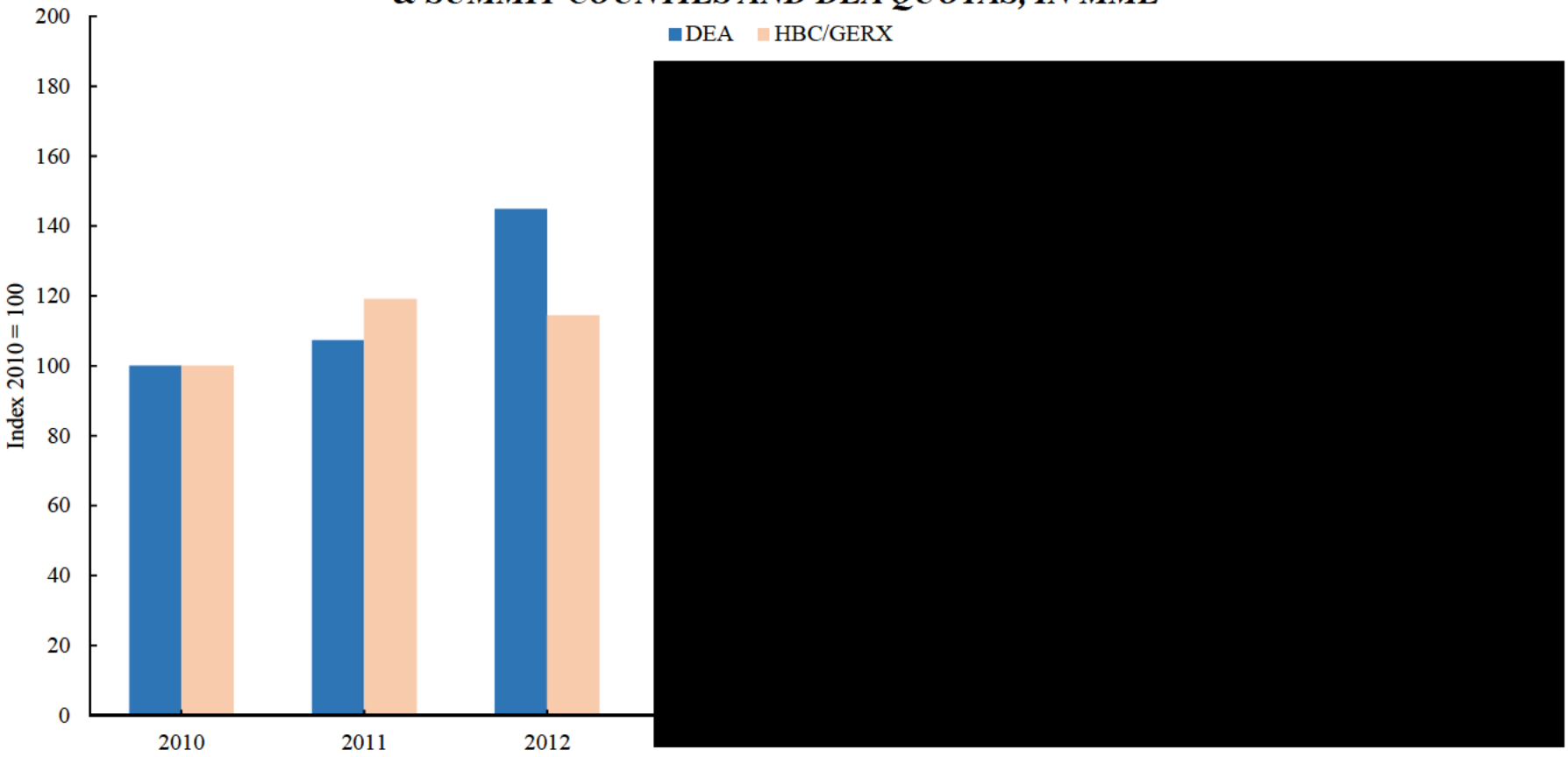
Sources:
"Cuyahoga and Summit by month 12 Drugs (Cardinal added)- Public ARCOS.xlsx," available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MDL Code Submission 4.23.2019\Expert Report Appendix 9 Macros\Appendix 9D\" and "HBC.xlsx" available at "...\MDL Code Submission 4.23.2019\MATLAB Code for Flagged Transactions\Code Production\Input Transactions\"

EXHIBIT F: TOTAL PER CAPITA MME SHIPPED IN SUMMIT COUNTY VS. PER CAPITA SHIPPED BY HBC/GERX

Note: Total MME per Cap in this chart is calculated using data from 3-digit zip code "443" as described in footnote 56 to the McCann Report. The values appear to vary from McCann Figure 23.

Sources:
"Cuyahoga and Summit by month 12 Drugs (Cardinal added)- Public ARCOS.xlsx," available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MDL Code Submission 4.23.2019\Expert Report Appendix 9 Macros\Appendix 9D\" and "HBC.xlsx" available at "...\MDL Code Submission 4.23.2019\MATLAB Code for Flagged Transactions\Code Production\Input Transactions\"

EXHIBIT G: INDEXED COMPARISON OF HBC HCP DISTRIBUTION IN CUYAHOGA & SUMMIT COUNTIES AND DEA QUOTAS, IN MME



Notes:
[1] HBC distributed HCP to Giant Eagle pharmacies from November 2009 to September 2014, and GERx began distributing HCP to Giant Eagle pharmacies in March 2016.
[2] Data is reported in MME, and is indexed to 2010 values.

Sources:
[A] "HBC_MDL00189212 (A1354473).xlsx" and "HBC_MDL00189213 (A1354474).xlsx."
[B] "Aggregate Production Quota History For Selected Substances," *DEA*, Harper-Avilla Exhibit 8.
[C] "full_ndc_dictionary.csv," available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MDL Code Submission 4.23.2019\ARCOS R code\Process ARCOS and Defendant data\dictionaries"
[D] Estimated oral morphine milligram equivalent (MME) conversion factors, available at https://www.cdc.gov/drugoverdose/resources/data html (last accessed May 10, 2019).

EXHIBIT H: TOTAL PRESCRIPTIONS AND CONTROL PRESCRIPTIONS FILLED BY GIANT EAGLE PHARMACIES IN CUYAHOGA & SUMMIT COUNTIES

November 2009 - May 2018

Pharmacy	Total Prescriptions	Control Prescriptions	Control Prescriptions / Total Prescriptions
0204-North Royalton	[redacted]	[redacted]	8.8%
0208-Lyndhurst	[redacted]	[redacted]	9.8%
0209-Bedford	[redacted]	[redacted]	8.4%
0217-Middleburg Heights	[redacted]	[redacted]	8.9%
0218-City View	[redacted]	[redacted]	9.1%
0224-Twinsburg	[redacted]	[redacted]	9.3%
0228-Solon	[redacted]	[redacted]	8.8%
0230-W. 117th Street	[redacted]	[redacted]	9.5%
0440-South Euclid	[redacted]	[redacted]	6.3%
0465-Brookpark	[redacted]	[redacted]	10.0%
1216-Westlake	[redacted]	[redacted]	10.2%
1263-Cleveland	[redacted]	[redacted]	11.4%
1297-Rocky River	[redacted]	[redacted]	10.0%
1298-Lorain Ave.	[redacted]	[redacted]	9.9%
1620-Green	[redacted]	[redacted]	12.3%
2108-Berea	[redacted]	[redacted]	10.1%
4009-Snow Rd.	[redacted]	[redacted]	8.8%
4025-Fairlawn	[redacted]	[redacted]	7.9%
4029-Springfield	[redacted]	[redacted]	11.8%
4030-Tallmadge	[redacted]	[redacted]	11.5%
4031-Barberton	[redacted]	[redacted]	13.9%
4032-Stow	[redacted]	[redacted]	10.1%
4036-Portage Crossing	[redacted]	[redacted]	10.0%
4086-Strongsville	[redacted]	[redacted]	9.8%
4087-Buckeye Rd	[redacted]	[redacted]	5.9%
4088-RT 82 and I-77	[redacted]	[redacted]	8.9%
4096-Stow	[redacted]	[redacted]	8.8%
4124-Waterloo Rd.	[redacted]	[redacted]	10.2%
5810-Fairview Park	[redacted]	[redacted]	9.0%
5817-Parma	[redacted]	[redacted]	10.1%
5830-Chagrin Blvd.	[redacted]	[redacted]	6.9%
5831-Detroit Ave/Lakewood	[redacted]	[redacted]	9.9%
5836-Mayfield Heights	[redacted]	[redacted]	9.4%
5861-Fairlawn	[redacted]	[redacted]	10.3%
5878-Howe Ave.	[redacted]	[redacted]	10.9%
6299-Macedonia	[redacted]	[redacted]	9.4%
6359-North Olmsted	[redacted]	[redacted]	8.8%
6376-Biddulph Rd.	[redacted]	[redacted]	10.1%
6388-Broadview Heights	[redacted]	[redacted]	8.8%
6414-Maple Heights	[redacted]	[redacted]	5.4%
Total	[redacted]	[redacted]	**9.8%**

Notes:

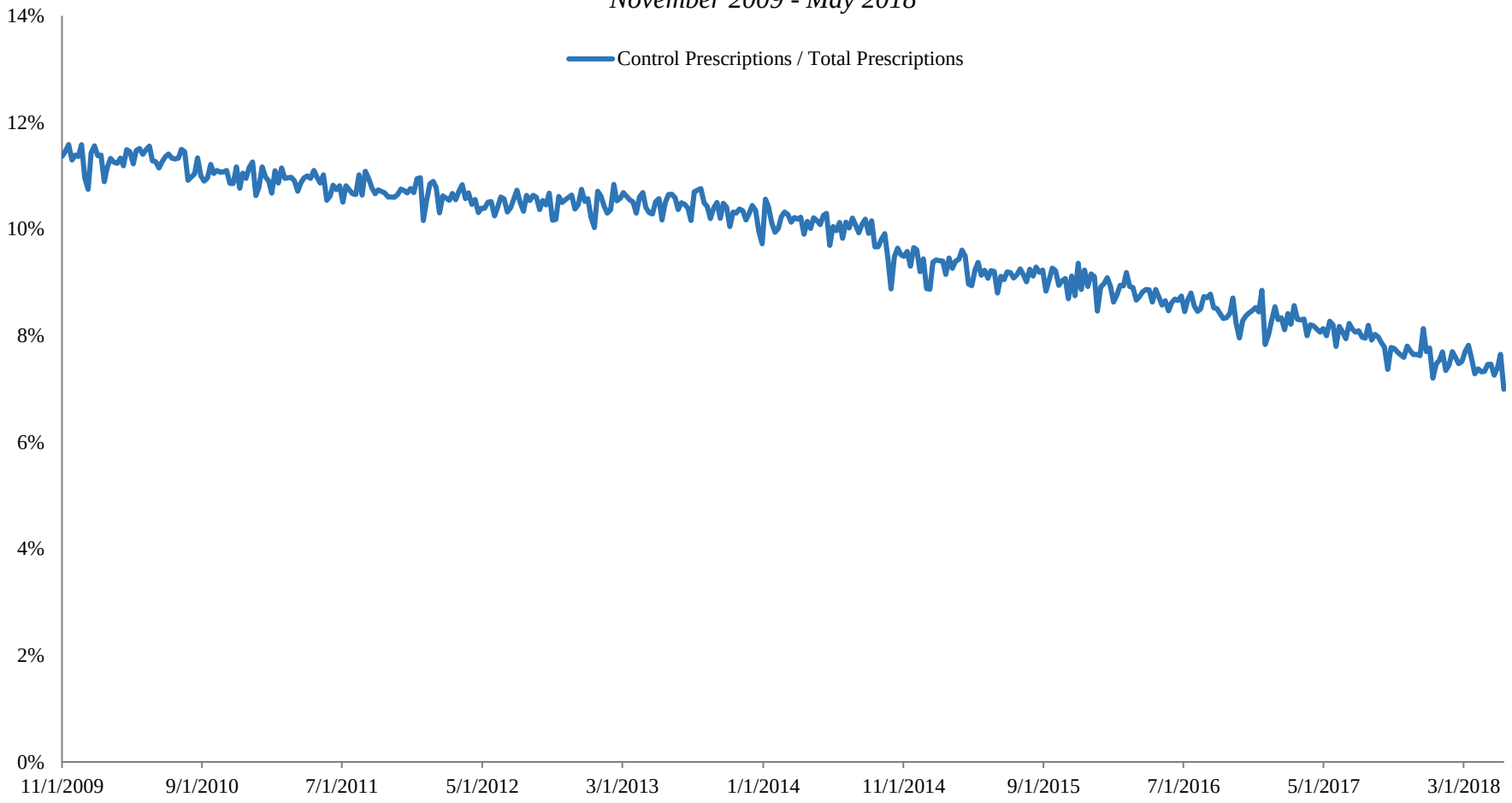
[1] Duplicate data for pharmacies 4032 and 5861 have been removed.

[2] Pharmacy numbers 0201 and 0228 refer to the same pharmacy. Data are combined as pharmacy number 0228.

Source: "Weekly Rx Volume by store (A1366710) xlsx"

EXHIBIT I: CONTROL PRESCRIPTIONS AS A SHARE OF ALL PRESCRIPTIONS FILLED (WEEKLY) BY GIANT EAGLE PHARMACIES IN CUYAHOGA & SUMMIT COUNTIES

November 2009 - May 2018



Note:
[1] Duplicate data for pharmacies 4032 and 5861 have been removed.

Source: "Weekly Rx Volume by store (A1366710).xlsx"

EXHIBIT J: GIANT EAGLE'S SHARE OF THE RETAIL PHARMACY MARKET FOR AT-ISSUE SUBSTANCES AND NON-CONTROLLED SUBSTANCES [1]

Giant Eagle "Market Footprint" Regions [2]

2014

	At-Issue Substances [3]	Non-Controlled Substances [4]
January	19.32%	25.13%
February	19.10%	24.86%
March	19.30%	24.82%
April	19.18%	24.70%
May	19.22%	24.47%
June	18.40%	24.43%
July	17.92%	23.33%
August	18.17%	23.04%
December	16.84%	22.63%
Annual Total	**18.60%**	**24.14%**

2015

	At-Issue Substances [3]	Non-Controlled Substances [4]
January	16.62%	24.19%
February	17.11%	24.02%
March	16.83%	23.85%
April	16.60%	23.14%
May	17.03%	23.17%
June	17.38%	23.27%
July	17.20%	22.93%
August	17.24%	22.79%
December	16.87%	22.81%
Annual Total	**16.99%**	**23.35%**

Notes:

[1] The market shares are calculated for the top 100 prescription drugs (as determined by IMS, based on Giant Eagle sales).

[2] Giant Eagle's Market Footprint includes all markets where Giant Eagle has a presence, which include Western Pennsylvania and parts of Ohio, West Virginia, Maryland, and Indiana.

[3] Giant Eagle's market share for at-issue substances is the total number of prescriptions filled by the company's pharmacies for HYCD/APAP, OXYCODONE HCL, and OXYCODONE/APAP, divided by the total number of prescriptions filled for the same three products by all pharmacies in the market.

[4] Giant Eagle's market share for non-controlled substances is the total number of prescriptions filled by the company's pharmacies for the non-controlled substances in the top 100 products, divided by the total number of prescriptions filled for the same non-controlled substances by all pharmacies in the market.

Sources: "HBC_MDL00181945 [Jan. 2015] xlsx," "HBC_MDL00181963 [Feb. 2015] xlsx," "HBC_MDL00181977 [Mar. 2015] xlsx," "HBC_MDL00181994 [Apr. 2015] xlsx," "HBC_MDL00182008 [May 2015] xlsx," "HBC_MDL00182025 [Jun. 2015] xlsx," "HBC_MDL00182033 [Jul. 2015] xlsx," "HBC_MDL00182044 [Aug. 2015] xlsx," "HBC_MDL00182063 [Dec. 2015] xlsx" (the sources listed herein and analyzed above are the only periods for which Giant Eagle has the relevant market share data—there are, therefore, some gaps in the listed months).

EXHIBIT J: GIANT EAGLE'S SHARE OF THE RETAIL PHARMACY MARKET FOR AT-ISSUE SUBSTANCES AND NON-CONTROLLED SUBSTANCES

At-Issue Substances (3)

HYCD/APAP	OXYCODONE HCL	OXYCODONE/APAP

Non-Controlled Substances (96)

ADVAIR DISKUS	AFLURIA	ALBUTEROL	ALLOPURINOL
AMITRIPTYLINE HCL	AMLODIPINE BESY	AMOX TR/POT CLAVUL	AMOXICILLIN
ATENOLOL	ATORVASTATIN CA	AZITHROMYCIN	BENZONATATE
BUPROPION HCL SR W	BUPROPION HCL XL	BUSPIRONE HCL	CARVEDILOL
CEFDINIR	CEPHALEXIN	CETIRIZINE HCL	CIPROFLOXACIN HCL
CITALOPRAM HBR	CLINDAMYCIN HCL	CLONIDINE HCL	CLOPIDOGREL BISULF
CRESTOR	CYCLOBENZAPRIN HCL	DILTIAZEM HCL	DOXYCYCLINE HYCLAT
DULOXETINE HCL	ESCITALOPRAM OXAL	FENOFIBRATE	FERROUS SULF
FLUARIX QUAD	FLUCONAZOLE	FLUOXETINE HCL	FLUTICASONE PROP
FLUVIRIN	FOLIC ACID	FUROSEMIDE	GABAPENTIN
GLIMEPIRIDE	HYDROCHLOROTHIAZIDE	IBUPROFEN (RX)	ISOSORBIDE MONONIT
LAMOTRIGINE	LANTUS SOLOSTAR	LEVOFLOXACIN	LEVOTHYROXINE SOD
LISINOPRIL	LISINOPRIL/HCTZ	LORATADINE	LOSARTAN POT
LOSARTAN POT/HCTZ	MELOXICAM	METFORMIN ER (G)	METFORMIN HCL
METHYLPREDNISOLONE	METOPROLOL SUCCIN	METOPROLOL TART	METRONIDAZOLE
MIRTAZAPINE	MONTELUKAST SOD	NAPROXEN	NEXIUM
OMEPRAZOLE (RX)	ONDANSETRON HCL	ONDANSETRON ODT	ONE TOUCH ULTRA
PANTOPRAZOLE SOD	PAROXETINE HCL	POTASSIUM CL	PRAVASTATIN SOD
PREDNISONE	PROAIR HFA	QUETIAPINE FUM	RANITIDINE HCL
SERTRALINE HCL	SIMVASTATIN	SMX/TMP	SPIRIVA HANDIHALER
SPIRONOLACTONE	SUMATRIPTAN SUCCIN	SYMBICORT	SYNTHROID
TAMIFLU	TAMSULOSIN HCL	TIZANIDINE HCL	TOPIRAMATE
TRAZODONE HCL	TRIAMCINOLONE ACTN	TRIAMTERENE/HCTZ	VALACYCLOVIR HCL
VENLAFAXINE HCL ER	VENTOLIN HFA	VIT D	WARFARIN SOD

Notes:

[1] Giant Eagle Pharmacy's Top 100 Products for January, February, March, April, May, June, July, August, December included a total of 112 unique products, as the top 100 products vary from month to month.

[2] In addition to the three at-issue substances and the ninety-six non-controlled substances listed above, "Giant Eagle Pharmacy's Top 100 Products" also included thirteen controlled substances that are not at-issue in this case: ALPRAZOLAM, AMPHETAMIN SALT ER, AMPHETAMINE SALTS, APAP/CD, CLONAZEPAM, DIAZEPAM, LORAZEPAM, LYRICA, METHYLPHENIDATE ER, SUBOXONE, TRAMADOL HCL, VYVANSE, and ZOLPIDEM TART.

Sources: "HBC_MDL00181945 [Jan. 2015] xlsx," "HBC_MDL00181963 [Feb. 2015] xlsx," "HBC_MDL00181977 [Mar. 2015].xlsx," "HBC_MDL00181994 [Apr. 2015].xlsx," "HBC_MDL00182008 [May 2015] xlsx," "HBC_MDL00182025 [Jun. 2015] xlsx," "HBC_MDL00182033 [Jul. 2015] xlsx," "HBC_MDL00182044 [Aug. 2015] xlsx," "HBC_MDL00182063 [Dec. 2015] xlsx" (the sources listed herein and analyzed above are the only periods for which Giant Eagle has the relevant market share data—there are, therefore, some gaps in the listed months).

EXHIBIT K: PATIENT INFORMATION SHEET FOR HYDROCODONE/ACETAMINOPHEN

epocrates®
an athenahealth service

Drug

hydrocodone/acetaminophen

generic

Patient Education - English

Show Spanish

- **Generic Name:** acetaminophen and hydrocodone
- **Pronounced:** a SEET a MIN oh fen and hye droe KOE done
- **Brand Names:** Hycet, Lorcet, Norco, Verdrocet, Vicodin, Xodol, Zamicet

What is the most important information I should know about acetaminophen and hydrocodone?

MISUSE OF OPIOID MEDICINE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH. Keep the medication in a place where others cannot get to it.

An overdose of acetaminophen can damage your liver or cause death. Call your doctor at once if you have pain in your upper stomach, loss of appetite, dark urine, or jaundice (yellowing of your skin or eyes).

Taking opioid medicine during pregnancy may cause life-threatening withdrawal symptoms in the newborn.

Fatal side effects can occur if you use opioid medicine with alcohol, or with other drugs that cause drowsiness or slow your breathing.

Stop taking this medicine and call your doctor right away if you have skin redness or a rash that spreads and causes blistering and peeling.

What is acetaminophen and hydrocodone?

Hydrocodone is an opioid pain medication, sometimes called a narcotic. Acetaminophen is a less potent pain reliever that increases the effects of hydrocodone.

Acetaminophen and hydrocodone is a combination medicine used to relieve moderate to severe pain.

Acetaminophen and hydrocodone may also be used for purposes not listed in this medication guide.

What should I discuss with my healthcare provider before taking acetaminophen and hydrocodone?


You should not use this medicine if you are allergic to acetaminophen or hydrocodone, or if you have:

- severe asthma or breathing problems; or
- a blockage in your stomach or intestines.

Tell your doctor if you have ever had:

- liver disease;
- a drug or alcohol addiction;
- kidney disease;
- a head injury or seizures;
- urination problems; or
- problems with your thyroid, pancreas, or gallbladder.


If you use opioid medicine while you are pregnant, your baby could become dependent on the drug. This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on opioids may need medical treatment for several weeks.


Do not breast-feed. This medicine can pass into breast milk and cause drowsiness, breathing problems, or death in a nursing baby.

How should I take acetaminophen and hydrocodone?

Follow all directions on your prescription label. *Never take this medicine in larger amounts, or for longer than prescribed. An overdose can damage your liver or cause death.* Tell your doctor if the medicine seems to stop working as well in relieving your pain.

Always check your bottle to make sure you have received the correct pills (same brand and type) of medicine prescribed by your doctor.


Never share this medicine with another person, especially someone with a history of drug abuse or addiction. MISUSE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH. Keep the medicine in a place where others cannot get to it. Selling or giving away acetaminophen and hydrocodone is against the law.

Measure *liquid medicine* carefully. Use the dosing syringe provided, or use a medicine dose-measuring device (not a kitchen spoon).

If you need surgery or medical tests, tell the doctor ahead of time that you are using this medicine.

You should not stop using this medicine suddenly. Follow your doctor's instructions about tapering your dose.


Store at room temperature away from moisture and heat. Keep track of your medicine. You should be aware if anyone is using it improperly or without a prescription.


Do not keep leftover opioid medication. *Just one dose can cause death in someone using this medicine accidentally or improperly.* Ask your pharmacist where to locate a drug take-back disposal program. If there is no take-back program, flush the unused medicine down the toilet.

What happens if I miss a dose?

Since this medicine is used for pain, you are not likely to miss a dose. Skip any missed dose if it is almost time for your next dose. *Do not* use two doses at one time.

What happens if I overdose?


Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. *An overdose of acetaminophen and hydrocodone can be fatal.*

The first signs of an acetaminophen overdose include loss of appetite, nausea, vomiting, stomach pain, sweating, and confusion or weakness. Later symptoms may include pain in your upper stomach, dark urine, and yellowing of your skin or the whites of your eyes.

Overdose can also cause severe muscle weakness, pinpoint pupils, very slow breathing, extreme drowsiness, or coma.

What should I avoid while taking acetaminophen and hydrocodone?


Avoid driving or operating machinery until you know how this medicine will affect you. Dizziness or drowsiness can cause falls, accidents, or severe injuries.


Do not drink alcohol. Dangerous side effects or death could occur.


Ask a doctor or pharmacist before using any other medicine that may contain acetaminophen (sometimes abbreviated as APAP). *Taking certain medications together can lead to a fatal overdose.*

What are the possible side effects of acetaminophen and hydrocodone?


Get emergency medical help if you have *signs of an allergic reaction:* hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Opioid medicine can slow or stop your breathing, and death may occur. A person caring for you should seek emergency medical attention if you have slow breathing with long pauses, blue colored lips, or if you are hard to wake up.


In rare cases, acetaminophen may cause a severe skin reaction that can be fatal. This could occur even if you have taken acetaminophen in the past and had no reaction. *Stop taking this medicine and call your doctor right away if you have skin redness or a rash that spreads and causes blistering and peeling.*


Call your doctor at once if you have:

- noisy breathing, sighing, shallow breathing;
- a light-headed feeling, like you might pass out;

- liver problems--nausea, upper stomach pain, tiredness, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes); or
- low cortisol levels-- nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness.

Seek medical attention right away if you have symptoms of serotonin syndrome, such as: agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Serious side effects may be more likely in older adults and those who are overweight, malnourished, or debilitated.

Long-term use of opioid medication may affect fertility (ability to have children) *in men or women.* It is not known whether opioid effects on fertility are permanent.

Common side effects include:

- dizziness, drowsiness, feeling tired;
- nausea, vomiting, stomach pain;
- constipation; or
- headache.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What other drugs will affect acetaminophen and hydrocodone?

You may have breathing problems or withdrawal symptoms if you start or stop taking certain other medicines. Tell your doctor if you also use an antibiotic, antifungal medication, heart or blood pressure medication, seizure medication, or medicine to treat HIV or hepatitis C.

Opioid medication can interact with many other drugs and cause dangerous side effects or death. Be sure your doctor knows if you also use:

- cold or allergy medicines, bronchodilator asthma/COPD medication, or a diuretic ("water pill");
- medicines for motion sickness, irritable bowel syndrome, or overactive bladder;
- other narcotic medications--opioid pain medicine or prescription cough medicine;
- a sedative like Valium--diazepam, alprazolam, lorazepam, Xanax, Klonopin, Versed, and others;
- drugs that make you sleepy or slow your breathing--a sleeping pill, muscle relaxer, medicine to treat mood disorders or mental illness;
- drugs that affect serotonin levels in your body--a stimulant, or medicine for depression, Parkinson's disease, migraine headaches, serious infections, or nausea and vomiting.

This list is not complete. Other drugs may affect acetaminophen and hydrocodone, including prescription and over-the-counter medicines, vitamins, and herbal products. *Not all possible interactions are listed here.*

Where can I get more information?

Your doctor or pharmacist can provide more information about acetaminophen and hydrocodone.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

EXHIBIT L: MEDICATION GUIDE FOR NORCO

Medication Guide
NORCO® (nor koe')
Hydrocodone Bitartrate and Acetaminophen Tablets, USP, CII

NORCO® is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid pain medicine, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about NORCO®:

- **Get emergency help right away if you take too much NORCO® (overdose).** When you first start taking NORCO® when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking NORCO® with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NORCO® tablets. They could die from taking it. Store NORCO® away from children and in a safe place to prevent stealing or abuse. Selling or giving away NORCO® tablets is against the law.

Do not take NORCO® if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- known hypersensitivity to hydrocodone or acetaminophen, or any ingredient in hydrocodone and acetaminophen tablets.

Before taking NORCO®, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of NORCO® during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breast feeding.** NORCO® passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NORCO® with certain other medicines can cause serious side effects that could lead to death.

When taking NORCO®:

- Do not change your dose. Take NORCO® exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every four to six hours as needed for pain.
- Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NORCO® regularly, do not stop taking NORCO® without talking to your healthcare provider.
- After you stop taking NORCO® tablets, the unused tablets should be disposed of by flushing down the toilet.

While taking NORCO® DO NOT:

- Drive or operate heavy machinery, until you know how NORCO® affects you. NORCO® can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with NORCO® may cause you to overdose and die.

The possible side effects of NORCO®:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of NORCO®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

For more information call Allergan at 1-800-678-1605
Manufactured by:
Warner Chilcott Company, LLC
Manati, Puerto Rico 00674

Distributed by:
Allergan USA, Inc.
Irvine, CA 92612

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 12/2016

EXHIBIT M: STORE GROWTH FROM THE THRESHOLD MONTH TO MONTH OF FIRST FLAGGED TRANSACTION – HCP

Dr. McCann's Maximum Monthly Trailing Six-Month Threshold Approach

Store	Store Address	County	Threshold Month [1]	Total Dosage Units in Threshold Month	Date of First Flagged Transaction	Total Dosage Units in Month of First Flagged Transaction	Store Growth (Prescriptions Filled) [2]	Control Prescriptions / Total Prescriptions	
								Threshold Month [1]	Month of First Flagged Transaction
#0218	5744 Transportation Blvd, Garfield Hts	Cuyahoga	Jun-10	9,330	8/29/2010	10,030	34%	11%	12%
#4029	2801 East Waterloo Road, Akron	Summit	Apr-10	16,460	5/30/2010	16,730	23%	14%	13%
#4031	41 5th Street Se, Barberton	Summit	Apr-10	33,660	5/28/2010	35,830	26%	18%	17%
#4087	11501 Buckeye Road, Cleveland	Cuyahoga	Feb-10	3,400	5/25/2010	4,100	21%	7%	7%

Notes:

[1] Dr. McCann defines the threshold month as the month within the previous six months with the highest amount of HCP distributed, measured in dosage units.

[2] Store growth is calculated as the growth in prescriptions filled from the threshold month to the month of the first flagged transaction.

Sources:

[A] "HBC xlsx," available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MCCANN 3.25.19\Distributor Transactions with Flag\"

[B] "Weekly Rx Volume by store (A1366710) xlsx"

EXHIBIT N: TRANSACTIONS FLAGGED BY DR. MCCANN BEFORE HBC BEGAN DISTRIBUTING OPIOIDS

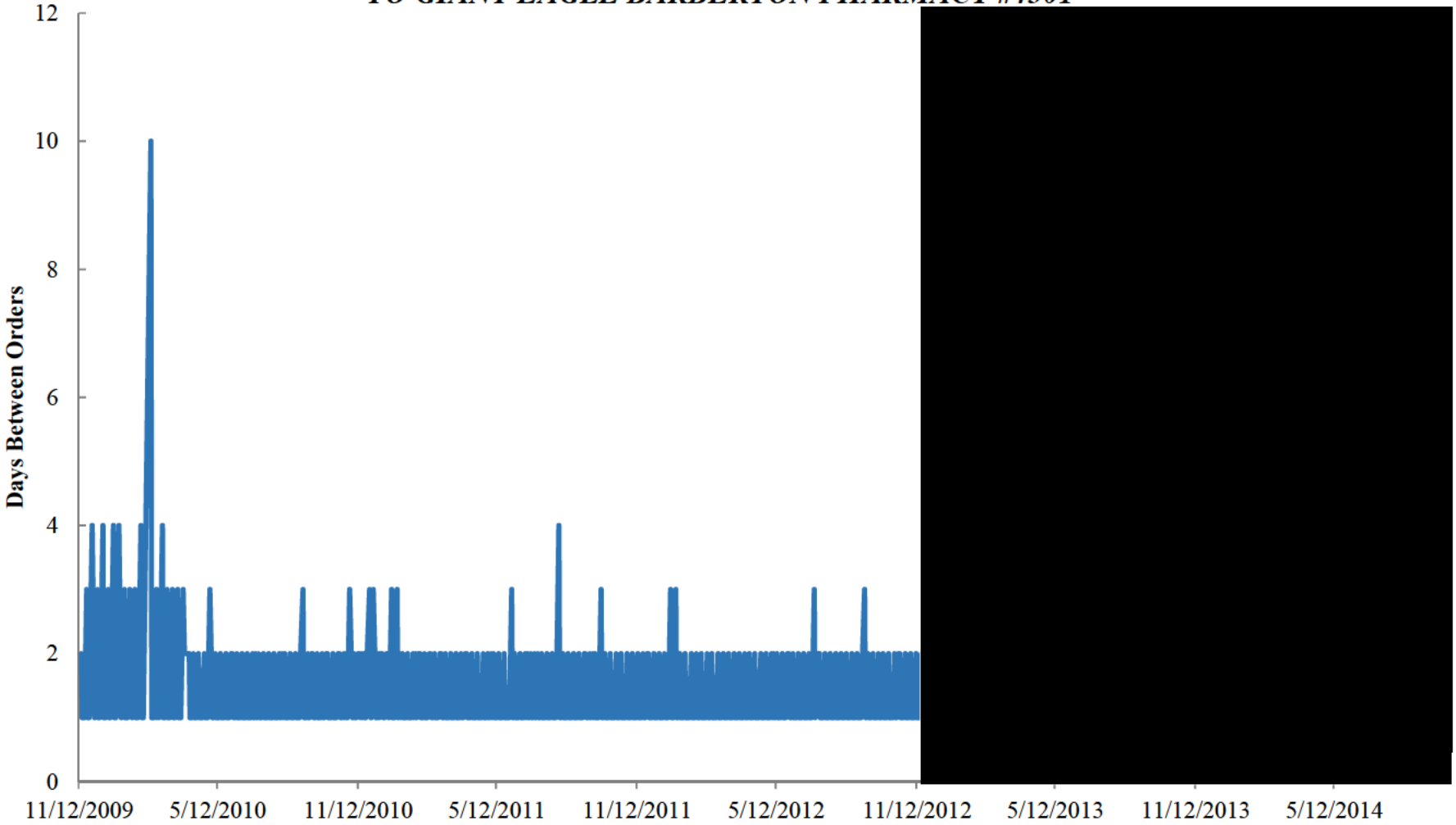
Chain Distributor Transaction Analysis

			Number of Flagged Transactions				
Drug	**Period**	**Total Number of Transactions**	**Maximum Monthly, Trailing Six-Month Threshold**	**Twice Trailing Twelve-Month Average Pharmacy Dosage Units**	**Three Times Trailing Twelve-Month Average Pharmacy Dosage Units**	**Maximum 8,000 Dosage Units Monthly**	**Maximum Daily Dosage Units**
Oxycodone	01/03/2006 - 12/31/2014	[redacted]					
HCP	01/03/2006 - 11/11/2009	50,783	41,568	4,447	2,656	23,890	42,547

Notes:
[1] HBC started distributing HCP to Giant Eagle pharmacies on November 12, 2009 and oxycodone on March 17, 2016.
[2] The date range for Dr. McCann's chain distributor analysis is January 1, 2006 - December 31, 2014.

Sources: Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 and "Giant Eagle.xlsx" file available in the reliance materials to the report at the location "...\MCCANN 3.25.19\Chain Distributor Transactions with Flag\Giant Eagle.xlsx."

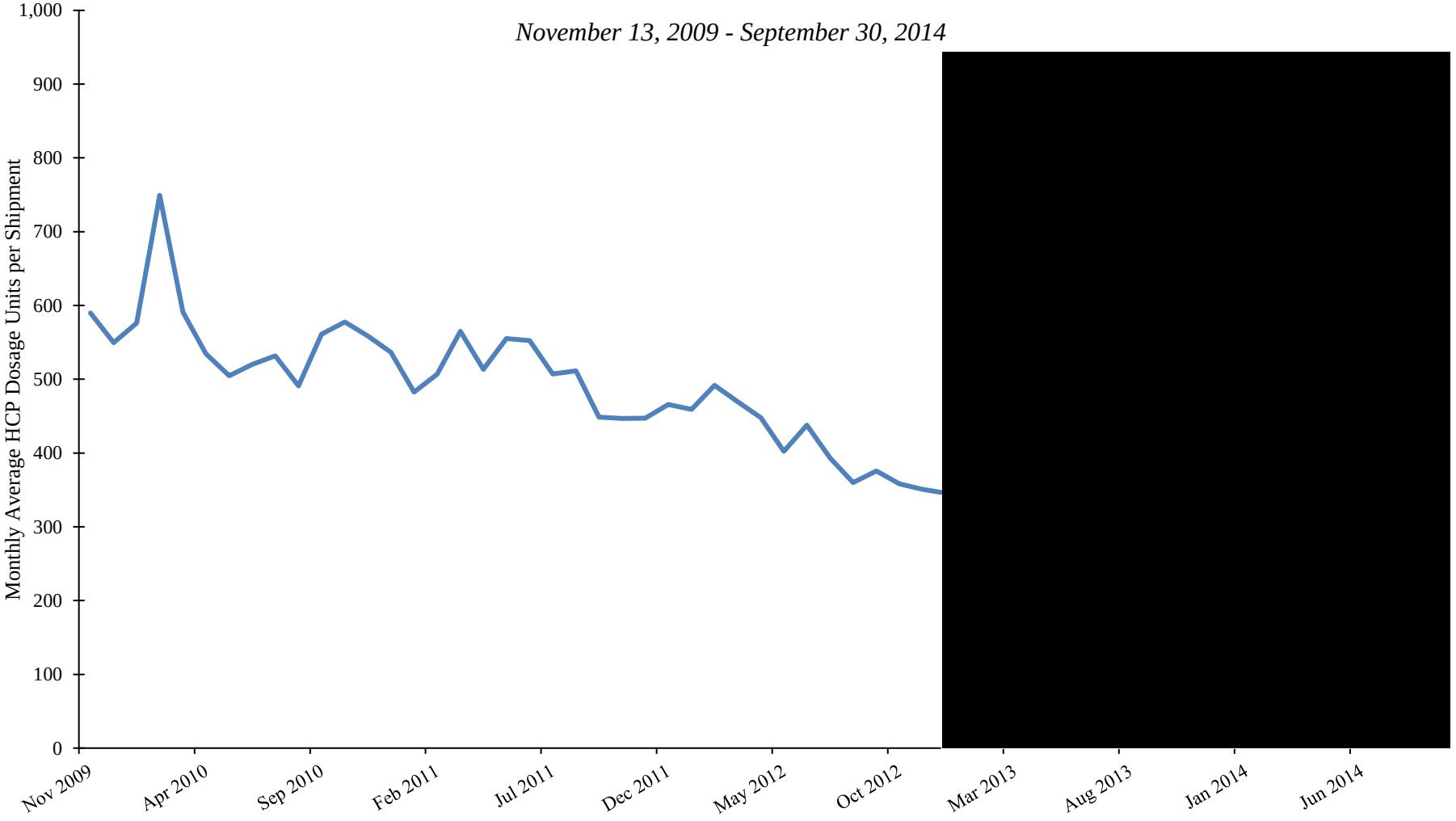
EXHIBIT O: DAYS BETWEEN ORDERS OF HYDROCODONE PRODUCTS FROM HBC SHIPPED TO GIANT EAGLE BARBERTON PHARMACY #4301



Note:
[1] Days between orders are calculated as the number of days between each of the unique dates that HBC shipped hydrocodone products to the Giant Eagle Barberton Pharmacy #4301.
Source: "HBC.xlsx" file available in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MCCANN 3.25.19\Distributor Transactions with Flag\HBC.xlsx"

EXHIBIT P: MONTHLY AVERAGE HCP DOSAGE UNITS PER SHIPMENT TO GIANT EAGLE PHARMACY #4301 (BARBERTON)

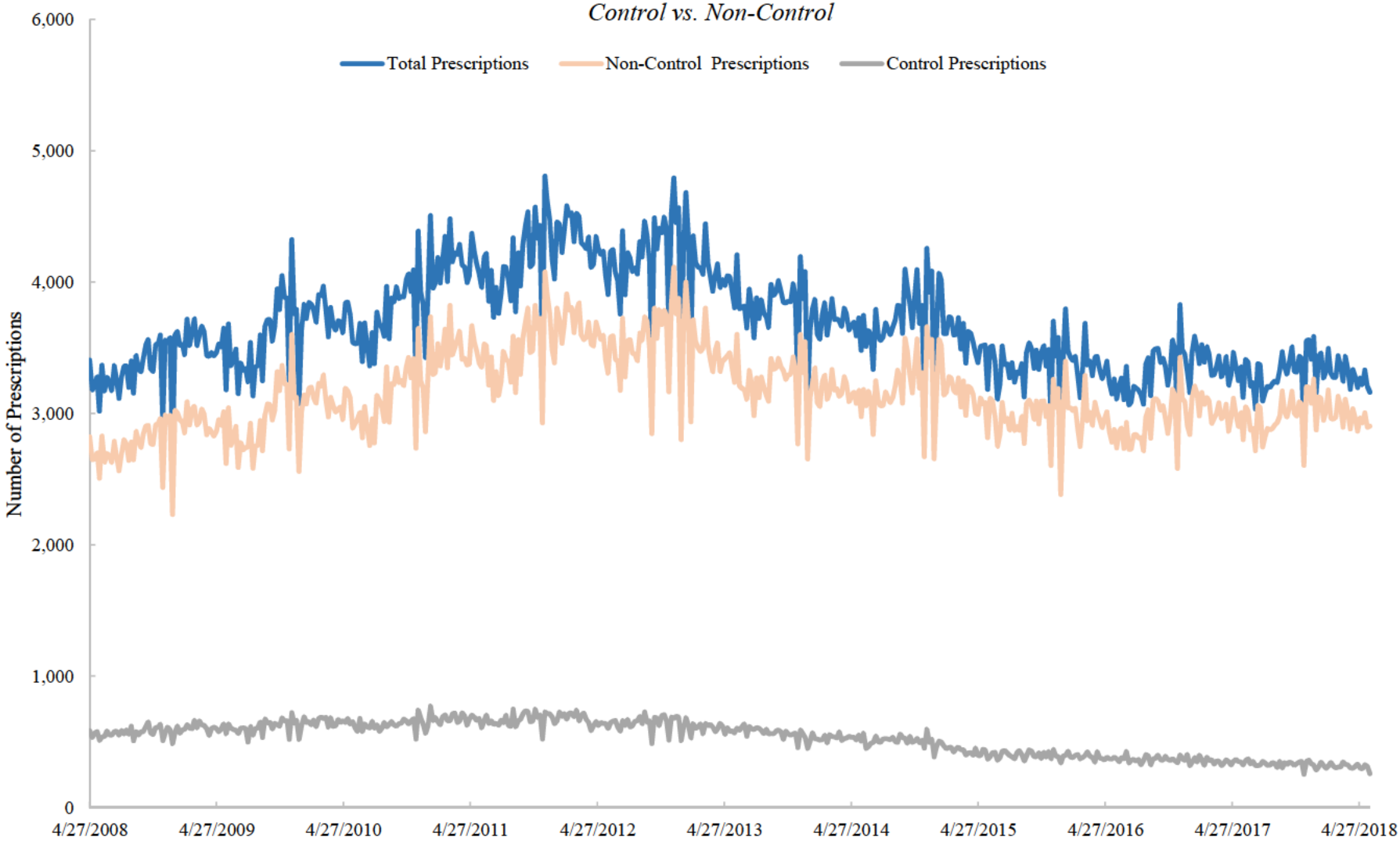
November 13, 2009 - September 30, 2014



Source: HBC transactions data in the reliance materials to the Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019 at the location "...\MDL Code Submission 4.23.2019\MATLAB Code for Flagged Transactions\Code Production\Input Transactions\HBC.xlsx"

EXHIBIT Q: NUMBER OF PRESCRIPTIONS FILLED (WEEKLY) BY GIANT EAGLE PHARMACY #4031 (BARBERTON)

Control vs. Non-Control



Source: "Weekly Rx Volume by store (A1366710).xlsx"